Isokinetic Line

Genu Iso – Genu Plus

User's Manual
Rev. C of the 16/07/2020
(Based on Italian Version F)

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CE GENU ISO

CE 1936 GENU PLUS

This apparatus is compliant to 93/42/CEE directive for medical equipments. Conformity has been tested according to CEI EN 60601-1 directive.

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1. INTRODUCTION

This manual applies to the equipment:

GENU-Iso CE

GENU-Plus CE1936

1.1 PURPOSE AND USE OF DEVICES IN THE LINE GENU

The devices in question are medical devices within the meaning of Article 1, paragraph 2 of Directive 93/42/EEC and subsequent amendments and additions, as it was intended to be used on humans for the purpose of rehabilitation therapy using dynamic action (motion isokinetic, hydrodynamic, isotonic, eccentric) or static (isometric).

The devices are intended for physical therapy in the field of rehabilitation and has been designed to allow the assessment and rehabilitation of the functions of flexion and extension of the muscles and knee joint.

In particular, on the basis of the definitions of the All. IX, Rule 9 of the Directive, it is:

- GENU-Iso: Medical treatment of class I.
- GENU-Plus: Any active medical device therapeutic class IIb.

Therefore it is a device to be used under direct medical supervision.
The devices are manufactured in compliance with Directive 93/42/EEC and subsequent amendments and additions.

1.2 ESSENTIAL PERFORMANCE

The device has no life support function for the patient. Non of its functions is indispensable expept those of movement control event in the event of single fault.

1.3 RESPONSIBILITIES OF EASYTECH

Easytech reserves the right to make changes and/or improvements to this manual and its products without prior notice. At the same time the manufacturer declines any whatsoever responsibility for damages or inconveniences arising from typographical errors contained in this manual.

Easytech declines any responsibility regarding the safety and functionality of Isokinec Devices, if:

- Installation, modifications, maintenance and inspections are not carried out by personnel authorized by Easytech.
- The device has been installed in a room with an electrical system that is not compliant with the requirements of current standards.
- The device is not used for the intended use or in accordance with the instructions provided in this manual.
- The device has been tampered with by unauthorized personnel.

2. SAFETY PRESCRIPTIONS

2.1 IN GENERAL

These devices have been designed in compliance with current laws and standards. However, the safety of patients and operators can be guaranteed only if the instructions concerning installation, warnings and regular inspections are duly followed. The following paragraphs illustrate in detail the warnings and prescriptions that must be followed, grouped by specific topics.

The device must to be used by qualified personnel only

2.2 WARNINGS CONCERNING INSTALLATION, MAINTENANCE AND REGULAR INSPECTIONS

- The installation site must be fitted with an electric system that is compliant with the requirements of current standards.
- ATTENTION: to prevent the risk of electrical shocks, these devices must be connected to grounded power supplies only. The devices are fitted with a connection for the equipotential node of the room in which they are installed. The manager of the center where the device is installed must regularly verify that this connection is not damaged.
- Verify that the rating of the power supply matches the requirements printed on the device nameplate.
- Before installing the device, verify that the packaging and its content are not damaged.
- Only use the power cord supplied with the device or, in all cases, the spare power cords supplied by Easytech. Although it is possible to purchase similar cable that offer good performances, their characteristics are not suitable to guarantee the compliance with standards according to which the device has been manufactured. In particular:
  - The lead section of the cable network must be at least 1mmq.
  - The length of mains cable must NOT be greater than 2m.

- Leads with an insufficient section or an excessive length or both do not guarantee the safety of the electrical components.
- As quoted in standard EN 60601-1-2 regarding electromagnetic compatibility: “the use of cable other than those specified in ..... may increase emissions and reduce the immunity of the device”.
- Do not use adaptors, multiple sockets or extensions to connect the device to the mains.
- Do not place heavy or sharp objects above the power cord in order not to damage it.
- Do not place the device next to heat sources or expose it to direct sun light. Install the device in an adequately ventilated room.
- Do not install the device in rooms with rapid temperature excursions or where humidity, dust, chemical vapors and vibrations are present.
- For information concerning electromagnetic interferences, refer to following paragraphs. Avoid installing the device close to potential sources of electromagnetic interferences (like portable or mobile radio-communication devices or medical devices that generate electromagnetic energy for therapeutic

and diagnostic purposes) which would exceed the limits recommended in the standards and thus affect the immunity of the device.

- For information on how to perform maintenance, calibration and regular inspection operations, refer to Chapter 7.

2.3 WARNINGS CONCERNING USAGE

- The device must be used by qualified personnel only.
- Do not open the closing guard of the device for any reason.
- Before performing any cleaning or maintenance operation, disconnect the device from the power supply and always refer to the instructions contained in Chapter 7.
- Do not spill or spray liquids on the device, including the hand-piece.
- Do not obstruct the ventilation openings or insert objects into them.
- Verify that the connection cables do not obstruct the movements of the device.
- Verify that the cables are not knotted or kinked.
- Frequently visually verify the conditions of the device and in particular those of the power cord and related connectors (verify that the plug contacts are not blackened, that there are no signs of overheating, mechanical deformations or visible damages, or worn sheath). These quick and simple operations, that do not cover all possible situations, help in many cases to prevent sudden malfunctions.
- If the device has fallen to the ground or the external casing is damaged or you reasonably suspect that the performance of the device has degraded, disconnect it from the power supply and contact the technical support of Easytech.
- If the connection cable is damaged or liquid has penetrated inside the device, disconnect it and contact the technical support of Easytech.

2.4 WARNINGS REGARDING ELECTROMAGNETIC INTERFERENCE

Genu-ISO and Genu-PLUS devices do not produce electromagnetic energy for therapeutic purposes or for their internal functions. Having been manufactured in compliance with current laws and regulations, they generate a minimum amount of electromagnetic energy only, similarly to other electronic devices that are not used for communication purposes. Therefore, they generally cause no disturbance to other devices or produce radiations that could be potentially harmful for people, that is the patient, operators and other people.

Inversely, Genu-ISO and Genu-PLUS have also been manufactured so that they are immune from the disturbances produced by other systems, upon condition that these are also compliant with standards and that, if they do emit electromagnetic radiations (for therapeutic or telecommunication purposes), they are maintained at an adequate distance in order to avoid interferences.

In the following tables is indicated the Standard specifications

Safety related to Emission (EN 60601-1-2)

Guidance and manufacturer's declaration – Electromagnetic emissions

Emission test	*Conformity*	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The appliance use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The appliance is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic Emissions CEI 61000-3-2	Class A	It is possible to use the device in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions Voltage fluctuations/flicker emission CEI 61000-3-3	Compliant	

Safety related to Immunity (EN 60601-1-2)

Guidance and manufacturer's declaration – Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity Test	Test Level	*Conformity*	Electromagnetic Environment - Guidance
Electrostatic discharge IEC 61000-4-2	± 2,4,8 kV contact ± 2,4,8,15 kV air	Compliant	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Fast transient/burst IEC 61000-4-4	±2 kV, 100 kHz for power supply lines	Compliant	Mains power quality should be that of a typical commercial or hospital environment.
Sovratensioni (surge) IEC 61000-4-5	±1KV differential mode ±2KV common mode	Compliant	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EC 61000-4-11	100% drop, 0/5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods	Compliant	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	Compliant

Guidance and manufacturer's declaration – Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity Test	Test Level	*Conformity*	Portable and mobile RF communication equipment should be used no closed to any part of the device, including cables, than the racommended separation distance calculated from the equation applicable to the frequency of the transmitter.
RF Conducted IEC 61000-4-6	from 150 KHz to 80 MHz	3 Veff (Standard A)	d = (6/E) * □P
	6,765-6,795 MHz 13,553-13,567 MHz 26,957-27,283 MHz 40,66-40,70 MHz	6 Veff	d = (6/E)*□P
RF radiated IEC 61000-4-3	80MHz ÷ 800 MHz	3 V/m (Standard A)	d = (6/E) *□P
(See note)	800MHz ÷ 2.7GHz	3 V/m (Standard A)	d = (6/E) * □P

In the equation, "d" is the recommended separation distance (in meters) and "P" is the maximum rated output power of the transmitter (in Watt) according to the manufacturer; "E" is the level of immunity; "*" is the multiplication symbol, " □□ " means square root.

Interference may occur near devices marked with the following symbol:

2.5 SPECIAL PRESCRIPTIONS FOR OPERATORS

There are no specific prescriptions for operators. If an operator wishes to test the operation of the device on his own body, he must simply follow the prescriptions for patients.

During the different phases of the exercises, the operator must:

- Supervise the exercise in order to be able to intervene in case of need.
- Use the device in accordance with the instructions contained in this manual and avoid performing any operation that could endanger himself and/or the patient.
- Verify that all safety distances are maintained during the active phase of the treatment in order to prevent potential collisions between the patient and other people or objects.
- Help elderly patients and patients that have difficulties in moving or that are unstable.
- Disconnect the device from the power supply and contact the technical support of Easytech if the connection cable is damaged or if liquid has penetrated in the device.

2.6 SPECIAL PRESCRIPTIONS FOR THE PATIENT

2.6.1 Contraindications

At present, Genu/Prima can be used by anyone provided that the physician/therapist defines the type, intensity and limits of the exercises in function of the ability and conditions of each patient.

The apparatus of the Isokinetic Line must not be used on pediatric patients.

2.6.2 Special cautions

The are no particular precautions to be taken in the use of the device, unless it verifies the correct positioning of the patient.

2.7 SAFETY DEVICES

If a power failure occurs on the 220V mains, when power resumes the device sets itself in standby mode and waits for the operator to select a function.

The device is also fitted with automatic safety devices that protect it from overcurrrents (fuses) and that are able to stop the device independently from the software.

It is provided an additional thermal control that stops the engine when the internal temperature goes too high.

The patient has available an emergency button that instantly cut the power to the electrical power of the appliance, making it inert. If the emergency button is pressed a message will appear on the screen of the PC **(no for concentric mode)**

3. DESCRIPTION OF GENU

3.1 STRUCTURE OF THE DEVICE AND TECHNICAL DESCRIPTION

The Genu unit has been designed to allow the evaluation and rehabilitation of flexion and extension functions of the muscles and knee joint.

The device (the element on the right in the figure) is composed of:

- A seat and a series of levers and connections for positioning the patient;
- A closed part containing the hydraulic gear-motor, the feeding system and the control system;
- A management and interface software

The device requires to be connected to a PC by a cable that allows the bidirectional transmission of data via USB connection. The Software on the PC allow the operator to configure the device in according to the modalities of the exercise/test, to receive the measurements relating to the exercise from the device and allow the storage and consultation of the data relating to the exercises performed. The program for managing tests, exercises, archives and utilities is developed in a Microsoft environment and can run on a PC with Microsoft operating system.

The active part of Genu is composed of on hydraulic gearmotor (consisting of a hydraulic pump, a distribution system and a hydraulic actuator) commanded by a solenoid valve and controlled by a dedicated electronic card with a microcontroller.

For the electrical safety the following consideration apply:

- Genu is equipped with a knurled link to the equipotential ground node of the room. The manager will have to assess whether and when to use this link.
- Genu and PC are separately connected to the electrical network and between them by optoisolators.
- PC station must be positioned outside the patient area. If the therapist does not consider this warning enough, it is necessary to equip the PC with additional ground.

The PC must be used exclusively for the operation on Genu device. Any other use of the PC than that indicated in this manual involves the risk of degradation or loss of the essential safety features of the device and the immediate interruption of the guarantee.

3.1.1 Frame and patient accommodation

- Frame entirely made from electro-welded steel.
- Electroplated visible parts (nickel-cadmium plating and plastics lining).
- ABS fairings.
- Chair and fastening attachments from high density polyurethane foam (90 Kg/m3) with neoprene foam inserts in the most stressed areas.
- Lining of chair and straps from embossed imitation leather.
- Straps from high-strength nylon woven fabric.
- Seat frame is designed to support patient up to 120 kg.
- Continuous adjustment of:
  - seat length;
  - backrest tilt;
  - lever length (with adjustment ruler).
- Discrete adjustment of:
  - Range Of Motion (0° - 105°) pitch 15
  - Angles for isometric exercise (0° - 90°), in step of 15°

3.1.2 Oleodynamic section - Isometry selector

- Isokinetic brake with cam actuator, velocity adjustment (in direct relation to flow rate) obtained through a proportional electrically operated valve with feedback control.
- The sensing instruments are incorporated in the actuator:
  - torque transmitter: strain-gauge torquemeter;
  - position transmitter: optical encoder.
- The oleo-dynamic isokinetic brake can be locked at fixed angles using the special mechanical selector for isometric measurements and exercises.
- The control level of the selector is situated on the front of the device.

3.1.3 Personal Computer and Software

The program for the management of tests, exercises, databases and utilities, developed in a Microsoft environment, can run on any personal computer with Microsoft operating system. The database management engine is Microsoft Access®.

Operating systems Windows 7, 8, 8.1, 10 offer the possibility of connecting the device to a remote support network in order to be able to perform the necessary checks and download in real time software and firmware updates from a remote site.

3.1.4 Main technical features

Isokinetic unit for the evaluation/rehabilitation of flexion / extension functions of knee muscles:

- minimum operating space required m. 2.00 x 2.70
- CONCENTRIC controlled speed: **40°/s – 400°/s**;
- ECCENTRIC controlled speed: 2**0°/s – 200°/s** - **GenuPLUS model**
- PASSIVE MOVEMENT controlled speed: **5° /s – 20°/s** - **GenuPLUS model**
- independent, separate adjustment for flexion/extension;
- minimum increase interval **1°/s**;
- travel with mechanical stop: **0°-105º**
- minimum electronic adjustment interval: **1°**;
- torque resolution: **1.5 Nm**;
- Max Torque: **600Nm (+/- 5%)**
- goniometer resolution: **1°**
- angles for isometric exercise (0° - 90°), in steps of 15°

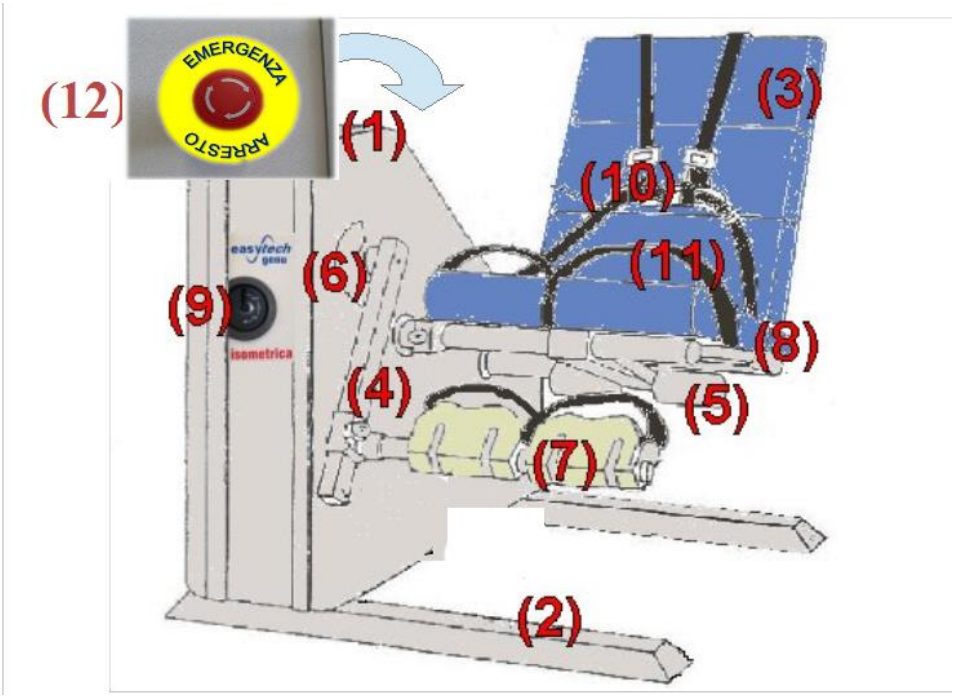
Electrical and mechanical characteristics of the parts that accommodate the patient (chair + levers system and actuator)

- power supply: **100-230V AC 50-60Hz, single-phase**;
- absorbed power: max **550VA**;
- fuses: retarded type **2xF6.3A (for Genu Plus); 2xF2A (for Genu Iso)**;
- duty: **continuous**;
- dimensions: m. **1.10 x 1.10 x 1.32**.
- weight: **Kg 150 (190Kg GENU Plus)**
- Environmental operating conditions:
  - temperature **10°C – 40°C**
  - relative humidity **0% - 75%** without condensed moisture.

Electrical characteristics of diagnostics console (trolley + computer + monitor + printer)

- Operating system: Windows 7,8,8.1,10
- Processor minimum requirements: Intel I3
- RAM minimum requirements: 4GB
- Video Board minimum requirements: 1024x768pixel 24bit
- Monitor: Compatible with video board.
- Printer: Color graphic compatible with personal computer & operating system
- USB port

3.2 DESCRIPTION OF THE DEVICE FUNCTIONS

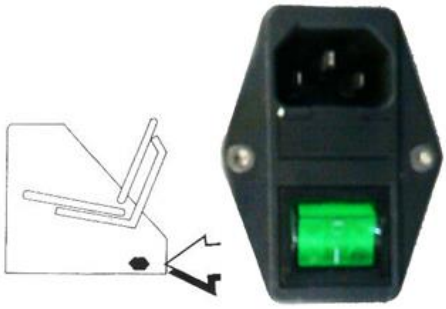


(1) Main body	(8) Handle
(2) Foot	(9) Isometric selector
(3) Backrest	(10) Belt (Shoulder and Abdomen)
(4) Lever	(11) Thigh strap
(5) Leg strap (idler arm) Used to prevent the limb under examination NOT impede the movements of the lever.	(12) Emergency Stop button: A provision of the patient for any eventuality. Causes the immediate stop of the machine and stopping the movement of the lever. Only in the model GenuPLUS
(6) Goniometer (Mechanical stops) Shown with guards removed for demonstration purposes only: NEVER WORK WITH THE GUARDS REMOVED!	
(7) Lever with standard ankle pad (right and left) or Lever with Anti Shear device (optional)	

4. CONNECTION TO GRID, FIRST TURN ON AND START PROGRAM

4.1 CONNECTION TO GRID

Insert the power cord to device and to grid (100-240 V 50/60 Hz)

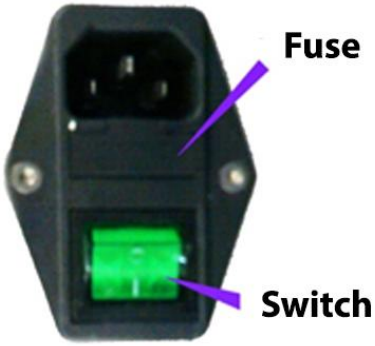


Make sure the Emergency Stop Button is in a raised position, if not, put it in its fully raised position by turning it as shown by the arrows.

Turn on the device by using the green switch, it will light up.

CHECKS TO BE PERFORMED IF THE DEVICE WILL NOT POWER ON

CHECK	SOLUTION
Is the grid power present in the device's installation site?	- Contact your own electrician
Is the power cord correctly connected to device? Is it intact?	- Connect the power cord whit care to device. Check the power cord and eventually replace it.
Is the main fuse good?	- Check the main fuse and replace if necessary.



If, after all checks are performed, the device still doesn't power on, refer to Easytech Technical assistance.

4.2 FIRST START-UP AND START OF THE PROGRAM

If the PC (Unit A) was bought from Esaytech to be used with Genu Unit, the software for device management is already pre-installed. Otherwise following the procedure illustrated in Appendix 1.

It is important that the software finds the mechanical part (Unit B) already on, therefore, please carefully follow the order in which the two units are turned on: first turn on unit B (mechanical part) and then turn on unit A (personal computer).

The personal computer is turned on by acting on the switch located on the front panel. Monitor and printer will turn on simultaneously as they are connected to the same circuit (verify that this occurs).

At the end of the boot phase of the operating system (Windows 7, 8, 8.1, 10) the monitor will display the windows desktop with the program start icon highlighted.

A double click on the "Isocine3" icon will activate the start of the "Isocine3.exe" program. The following image will appear:

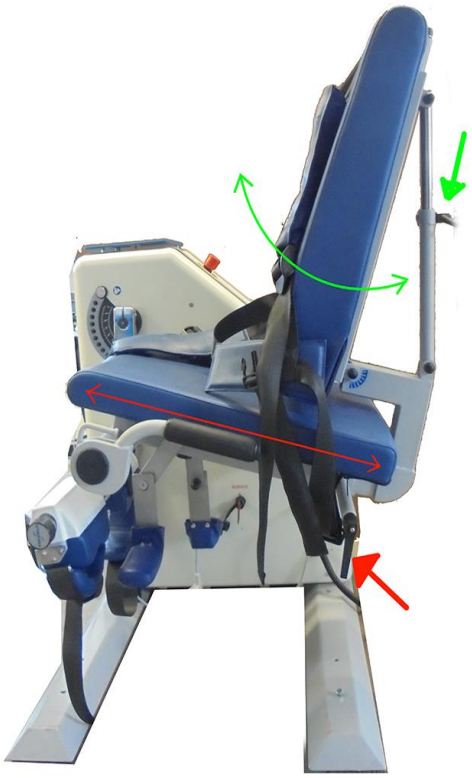
If the two units were turned on in reverse order, the PC would have no way to sending the appropriate setup instructions to the mechanics control board.

In case of communication error refer to paragraph 4.4.1.

4.3 MECHANICAL APPROACH

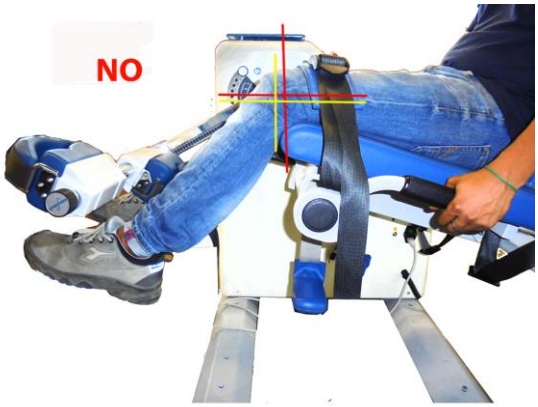
4.3.1 Patient's positioning and leverages

The chair consists of two sections. The seat is adjustable in length by sliding the backrest forward or aft after suitably operating the locking mechanism on the left side of the seat.



Backrest tilt can be adjusted by using the adjustment lever located on the rear side of the backrest.

It is essential that seat and backrest are adjusted as required to have the knee rotation fulcrum coincide with the lever rotation fulcrum. The back of the knee (popliteal region) must rest on the front seat edge.

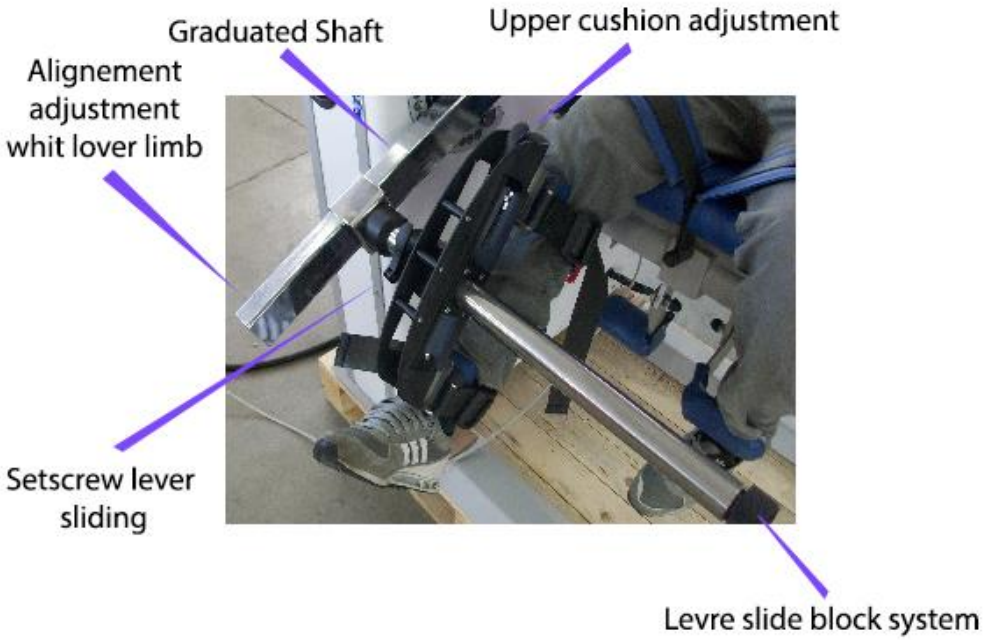


Adjust the lever length so that it matches the length of the patient's lower limbs by acting on the black locking knob located at the end of the cross lever that slides along the graduated rod (Figure below). The ankle support pad should normally rest on the lower part of the tibia. If only a left or right only exercise is carried out, the unused ankle pad must be kept in the locked position (pad pointing in the direction opposite to the patient).

If you intend to use the lever with the Anti Shear device, first remove the lever with the ankle pad installed on the graduated shaft; to do this remove the setscrew near the lower end on the graduated shaft then loosen the black blocking knob placed at the end of the cross-lever and pull out the lever with the ankle pad.
Insert the lever with Anti Shear device on the graduated shaft and lock it by pressing the black blocking knob placed at the lower end of the cross-lever.

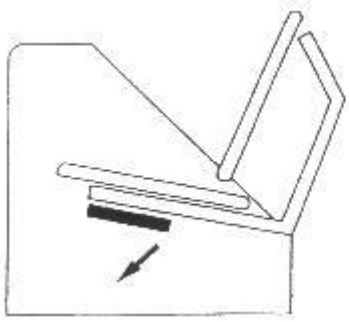
Replace the setscrew on the lever placed at the lower end of the graduated shaft.

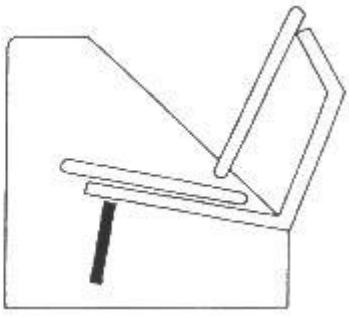
The lower cushion of the ankle pad must still be placed on the lower part of the tibia (ankle), the upper one must be set on the top of the tibia (under the knee), and the cross-tube of the lever, which constitutes the fulcrum of the Anti Shear ankle pad, must be positioned in an intermediate point between the two cushions, normally approximately in the middle; the most suitable position is determined by the therapist based on his experience and on the patient's particular problem.



Lever with Anti Shear device

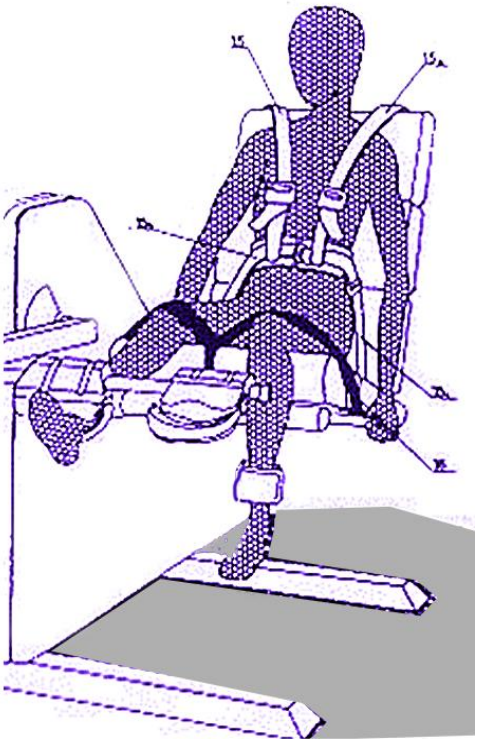
A clamping device is installed under the seat. It is used to hold the unused limb in case of isokinetic exercise of one limb only.





Attach the thigh straps by routing them under the hooks in the handle support rings. The four attachment-point harness is correctly positioned when the clasp is located immediately above the pubis. Adjust the harness by acting on the buckles that adjust the length of the lap and shoulder (torso) straps.

It is recommended that a towel be placed on the seat to guarantee hygiene and comfort and to limit wear and tear of the seat upholstery.

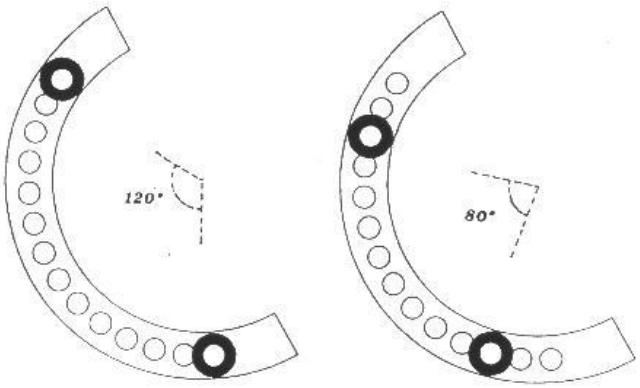


4.3.2 Adjustments for dynamic exercises

It is possible to perform the following independent adjustments:

- Angular velocity of extensors: between 40°/s and 400°/s in 1°/s steps;
- Angular velocity of flexors: between 40°/s and 400°/s in 1°/s steps;
- Angular velocity of eccentric extension: between 20°/sec and 200°/sec at 1°/sec steps; GenuPLUS model
- Eccentric bending angular velocity: between 20°/sec and 200°/sec at 1°/sec steps; GenuPLUS model
- Angular velocity of Passive Motion: Between 5°/sec and 20°/sec at 1 sec. Steps; GenuPLUS model
- Range Of Motion (ROM) of extensors: between 0° and 105° in 15° steps;
- ROM of flexors: between 0° and 105° in 15° steps;

For dynamic exercises, it is possible to limit the movement range for the exercises by tightening the knobs in the position that corresponds to the desired movement range.



Per accedere ai pomelli è necessario rimuovere la protezione leva, utilizzando l'apposito attrezzo

Pulsante di emergenza

Protezione trasparente contro urti o schiacciamenti
NON RIMUOVERE

4.3.3 Adjustments for static exercises

For instructions on how to set the isometric function during static exercises, refer to the previous figure.

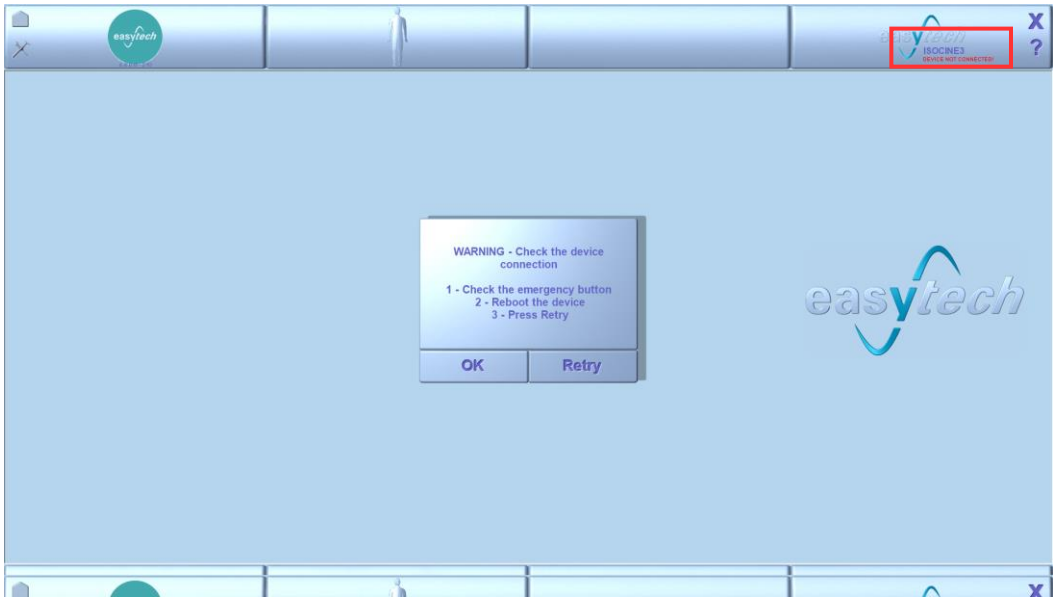
Move the selector to position ON and lock the lever in place at the desired angle (0°-90° in steps of 15°) to perform the isometric exercise.

Move the selector to position OFF to release the lever and perform dynamic exercises (isokinetic, hydrodynamic and isotonic).

4.4 POSSIBLE FAULTS

4.4.1 Communication error

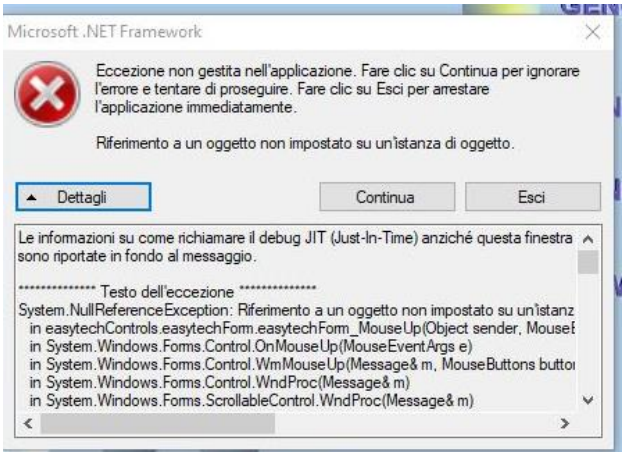
The communication between the two units is controlled upon start-up and when a new exercise/test is started.
In case of communication error between Pc and Genu unit, the following error will be displayed and in the program screen there will be a red writing in the upper right corner under the Easytech logo (Device not Connected):



Possible causes can be:

1. The USB Cable is not connected to the computer
2. The device is not turned on
3. The emergency button is pressed

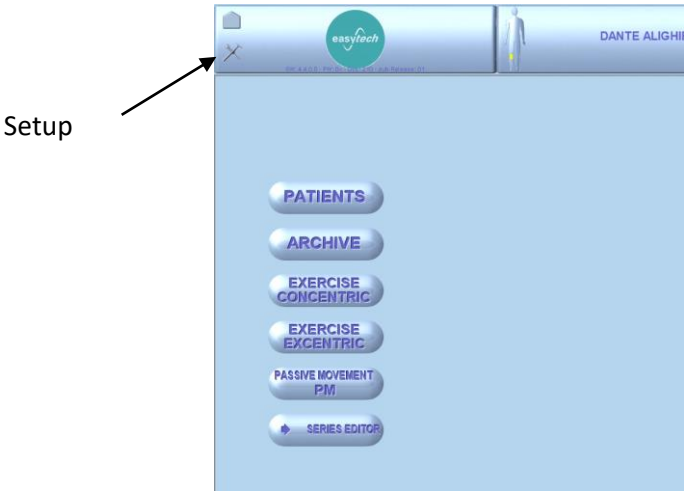
Check the USB connection, turn on the device or release the emergency button and press “Retry”.
If the program does not detect the device, set the parameters as indicated in Appendix 1 to the paragraph relating to the start of the program with an error message.
In some cases of communication error, the following error message may appear:


Microsoft .NET Framework
Eccezione non gestita nell'applicazione. Fare clic su Continua per ignorare l'errore e tentare di proseguire. Fare clic su Esci per arrestare l'applicazione immediatamente.
Riferimento a un oggetto non impostato su un'istanza di oggetto.
Dettagli
Continua
Esci
Le informazioni su come richiamare il debug JIT (Just-In-Time) anziché questa finestra sono riportate in fondo al messaggio.
********** Testo dell'eccezione **********
System.NullReferenceException: Riferimento a un oggetto non impostato su un'istanz
in easytechControls.easytechForm.easytechForm_MouseUp(Object sender, MouseE
in System.Windows.Forms.Control.OnMouseUp(MouseEventArgs e)
in System.Windows.Forms.Control.WmMouseUp(Message& m, MouseButtons butto
in System.Windows.Forms.Control.WndProc(Message& m)
in System.Windows.Forms.ScrollableControl.WndProc(Message& m)

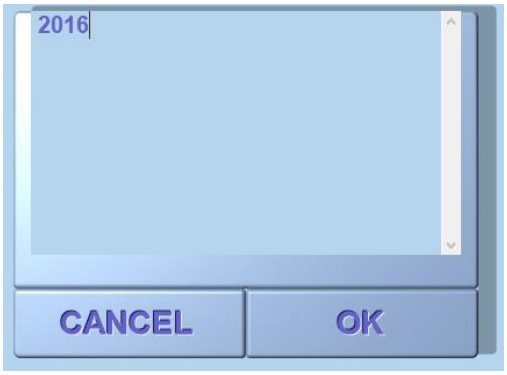
In these cases, write down the message on a note pad, and continue operating by pressing the “Continue” button.
Contact customer service if the error repeats frequently.

4.4.2 Procedure for air elimination

In case of anomalous movements of the lever during concentric exercise access the setup from the main screen:

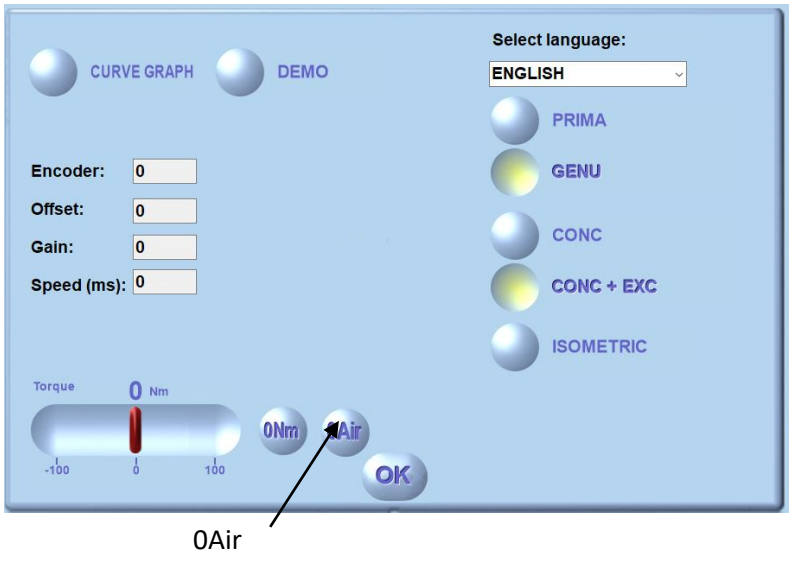


Enter the password “2016” and press ok.



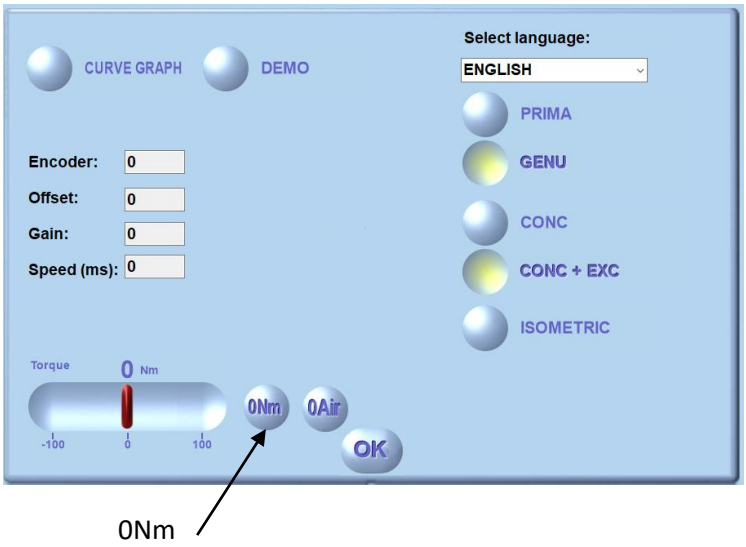
This will open the following window. Click on “0 Air” and follow the instructions on the screen.

NB: Make sure that the device is connected and switched on before starting the procedure.



4.4.3 Procedure for torque offset reset

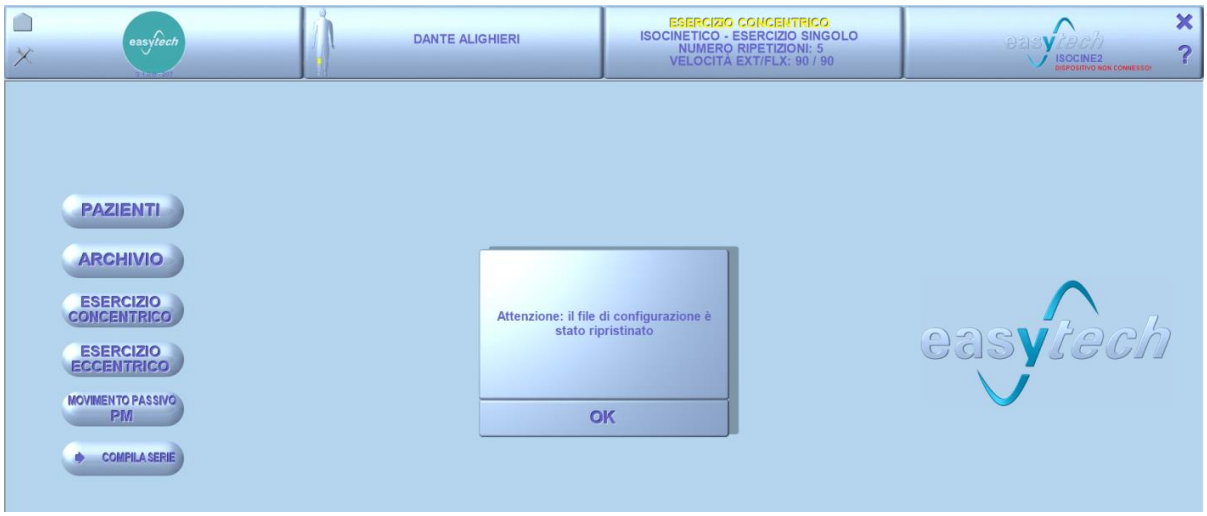
In case an offset is noticed on torque indication, it is possible to reset the torque value. Enter the setup following the steps indicated in the previous paragraph and click on “0Nm” button and following the instructions on the screen.



4.4.4 Notice recovery of configuration files

There is a possibility that a configuration file error might occur when the program starts up. An automatic file retrieval mechanism has been implemented, the program retrieves a copy of the saved configuration file at the end of the previous working session and restores it successfully.

Through the following message the program notifies the operator of the error resolution.



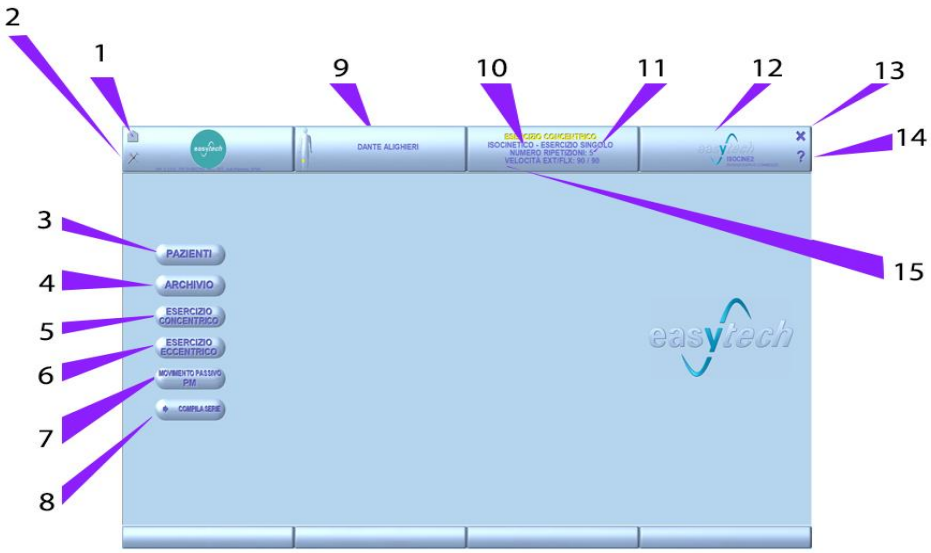
Click the "OK" button and proceed with a normal working session.
If the error persists, contact our service center.

5. PROCEDURES FOR PERFORMING THE EXERCISES

<u>Warning</u>: the indications given below refer to the program of the most complete model (Genu Plus) and therefore also refer to functions not provided for Genu Iso. Obviously, the operational configuration of the program installed on the different models is consistent with the features supported.

5.1 MAIN SCREEN

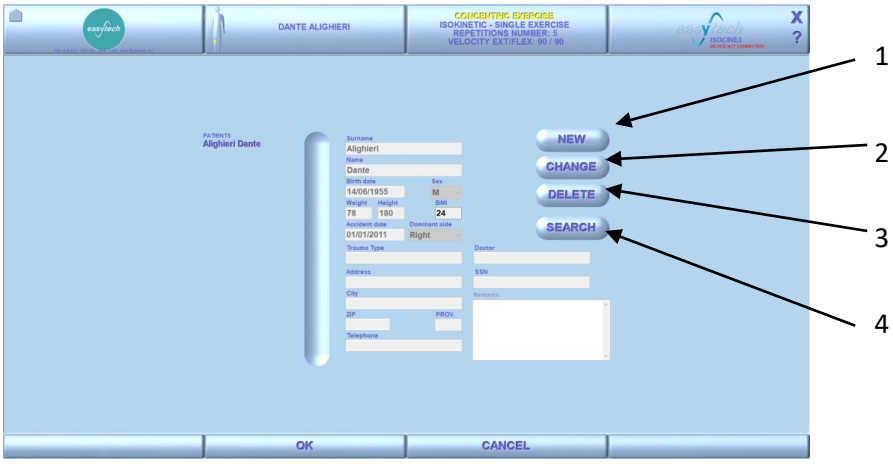
When the device is started, the following screen will display. This is the main screen of the program (home page) that can be used to access all the functions of the system.



1. HomePage	2. Settings
3. Patient page	4. Session log page
5. Concentric exercise	6. Eccentric exercise
7. Passive movements	8. Series preparation
9. Patient's name	10. Type of motion and operational mode
11. Number of repetitions	12. Device connection status
13. Close	14. Guide
15. Speed indications	

Controls can be selected with the mouse, with the function keys and through the touchscreen. These options are available also for subsequent controls.

5.2 PATIENT SELECTION



It is possible both to select patients that are already present in the database by clicking the list in the upper left and insert new names. All fields are accessible and editable. Upon start-up, the program displays the patient that has been selected during the previous session before the device was shutdown. The selected patient is the one to which the subsequent exercise will be linked in the database and whose data will be available for review.
Press OK to confirm.

To enter a new patient, press 1 (NEW), insert the desired data, press SAVE to save and OK to confirm.
To change the data, press button 2 (CHANGE), to delete them press button 3 (DELETE).

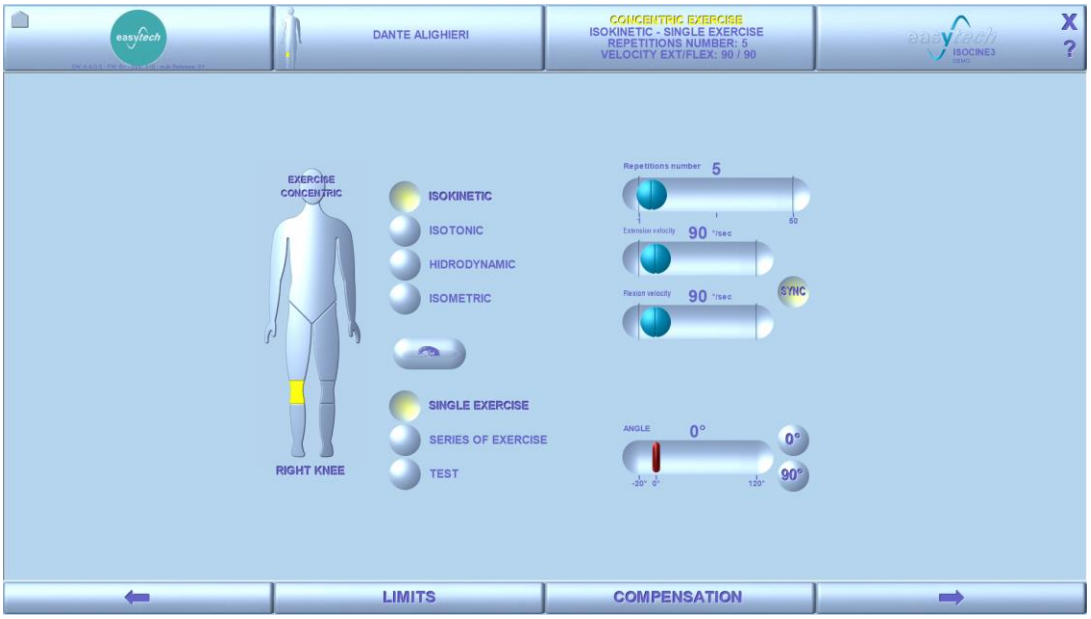
To search and recall a patient in the archive, press button 4 (SEARCH).

Entering a part of the patient's last name or SSN in their respective fields in the following window can be invoked by a patient in the archive.

If the search finds more than one match, select the desired patient among the listed ones.

5.3 CONCENTRIC EXERCISE

By selecting the “CONCENTRIC EXERCISE” from the main page, the following window will open:



The operator can use the virtual buttons to select:

- **Type of motion** (isokinetic, isotonic, hydrodynamic, isometric)
- **Type of exercise** (single exercise, series, test)
- **Segment to treat** (**GENU**: knee)

5.3.1 Concentric isokinetic exercise

5.3.1.1 Single exercise parameter settings

When a limb is selected, it is also necessary to change all the information displayed on the screen and printouts that contain the names of the movements and muscles involved in the exercise.

SEGMENT	MUSCLES INVOLVED	MOVEMENTS
Knee	Flexor and extensor muscles	Flexion/extension

In the following paragraph, every time the expression generic movement is used (with no reference to a specific limb), it refers to the muscles and movements of the knee, that is to a flexion/extension movement.

Selection of the LIMB - Move the mouse over the figure of the human body and click the desired limb.

Setting the ANGLE – This phase is used to calibrate the encoder. Position the patient correctly (as instructions in section 4.3.1), attaching the lever to the ankle using the system provided. Fully extend the leg and press the 0° button to save the position. Eventually it is possible to do the same thing for 90° (bent leg). It is advisable to set the parameters when the leg is extended (0°), unless the therapist judges that it is impossible.

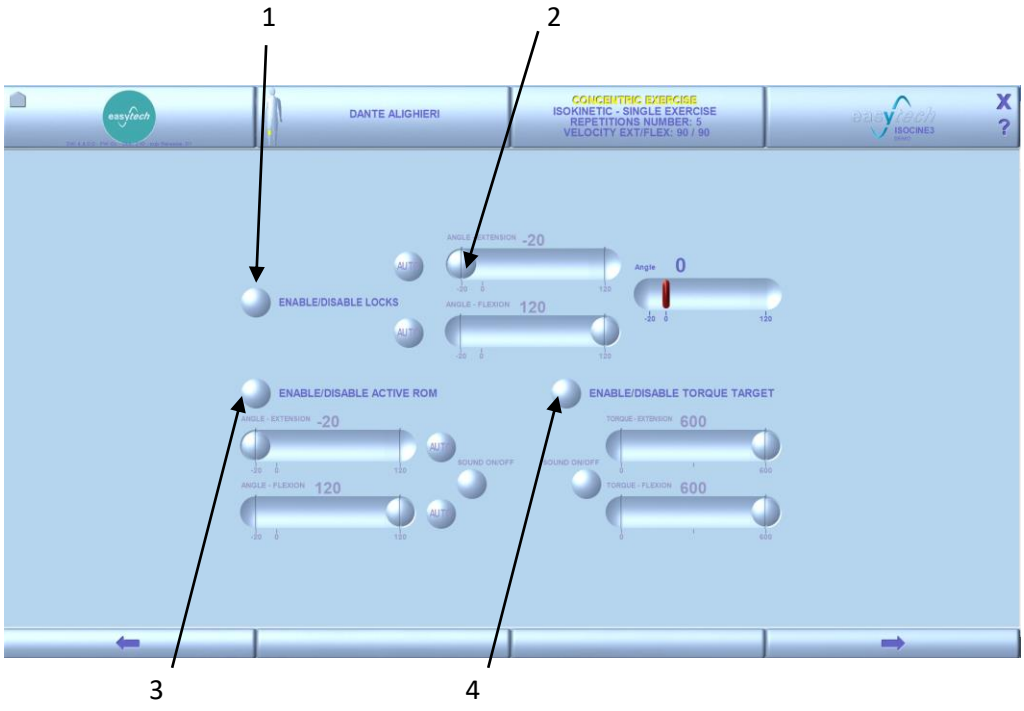
Number of repetitions – Move the cursor until the desired number displays and move the mouse to the right or left in increments of units for a fine adjustment.

Extension/flexion speed - Set the desired value by moving the cursor. Move the cursor to the right or left in increments of units for a fine adjustment.

SYNCRO – The extension/flexion values will be the same.

To move to the next step, select LIMITS SETTING or COMPENSATION.

5.3.1.2 Setting the limits



1 - ENABLE/DISABLE LOCK – Enable/Disable software blocks at flexion/extension angle.

2 – SET ANGLES AND LIMIT (Soft stop) - Use this option to set a limitation for the limb range. Setting limit angles during the exercise ensures that the limb moves only within the set arc, as if there were physical stops.
In order to correctly position the limit angles, it is first necessary to set the correct limb angle:

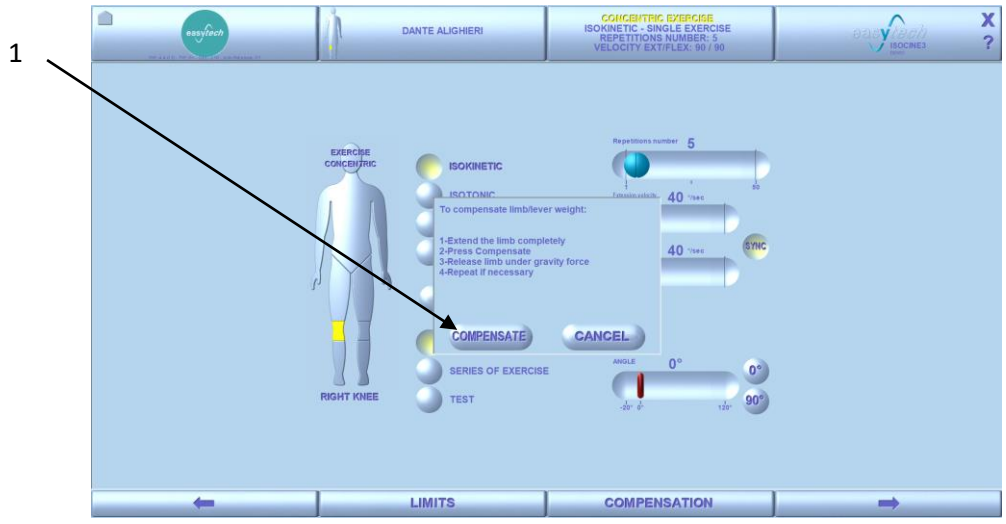
- Move the limb as far as the flexion limit angle and press button Auto next to the option for setting the flexion limit angle.
- Move the limb as far as the extension limit angle and press button Auto next to the option for setting the extension limit angle.

3 - ENABLE/DISABLE ACTIVE ROM (Range of movement) – Use this option to limit the range used to process the exercise data.

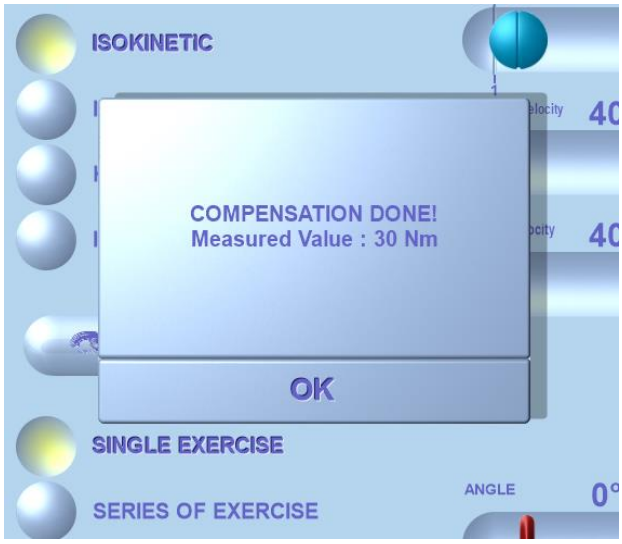
4 - ENABLE/DISABLE TORQUE TARGET – Use this option to display on the chart during the exercise a limit that the patient can refer to as the target to be reached. By default, this corresponds to the maximum value of the previous exercise.

5.3.1.3 Gravity compensation

This operation compensates the weight of the lever and limb being treated and ensures that the results are accurate.
To access to the gravity compensation window from the limit settings screen, press the BACK arrow and thus return to the main screen of the concentric exercise. From here it is possible to access the COMPENSATION tab through the relative button. This will open the following window:

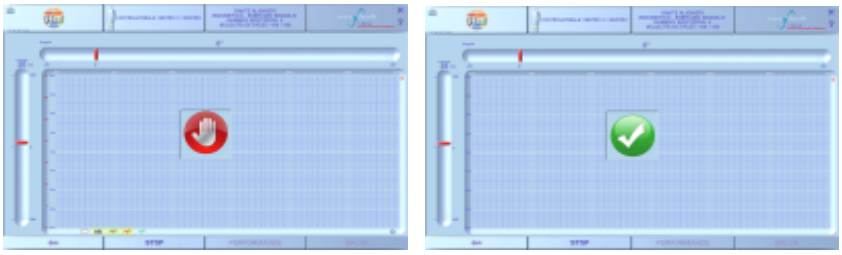


Position the patient following the instructions provided, extend the limb, press button 1 (COMPENSATE) and wait for the device to perform the compensation without forcing the operation (2 sec).
If the patient is the same, it is not necessary to repeat this operation at the beginning of each exercise, because the parameters are stored in the memory of the device. The therapist should compare the resulting value with the historical values to verify that the calibration is correct.
A confirmation screen will be displayed at the end of the operation:

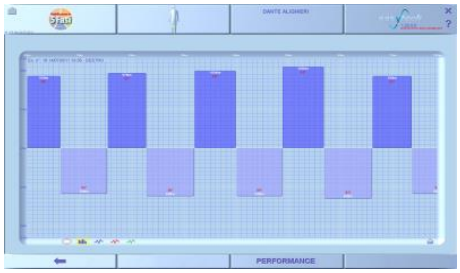


5.3.1.4 Exercise in progress

Once all the settings have been completed, press the arrow at the bottom right to access the page relating to the exercise.
Press START, wait for the device to issue an acoustic/visual signal, then start the exercise.

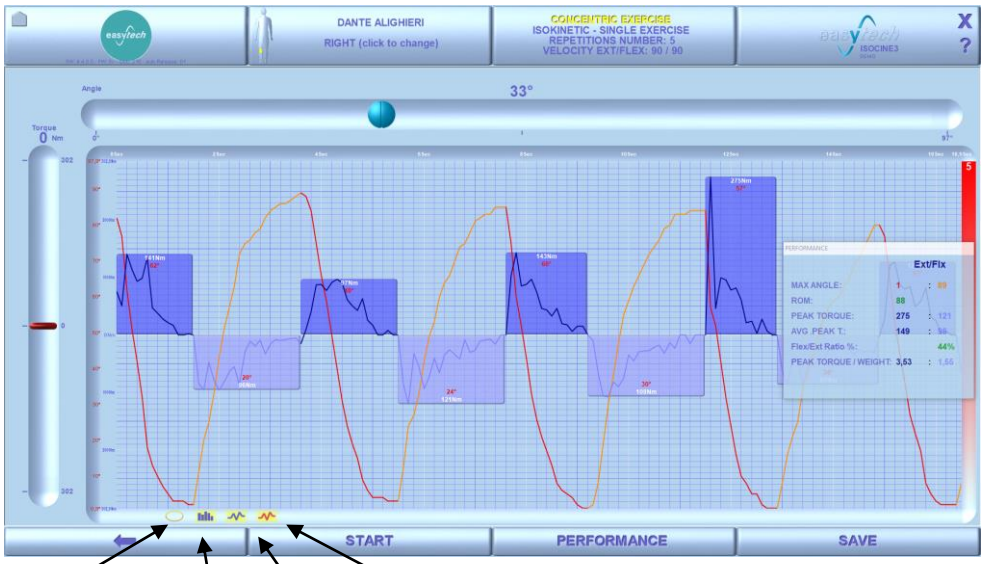


The actual exercise starts when the patient makes the first movement. During the exercise, the system displays in real time the histograms of the maximum torque values (peak torque) applicable to each movement.

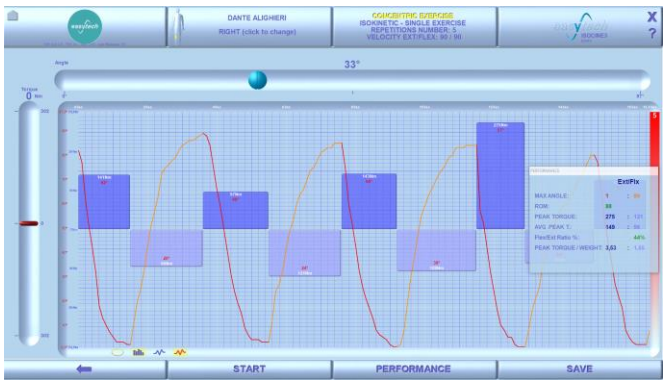


5.3.1.5 End of exercise and review of the graphics

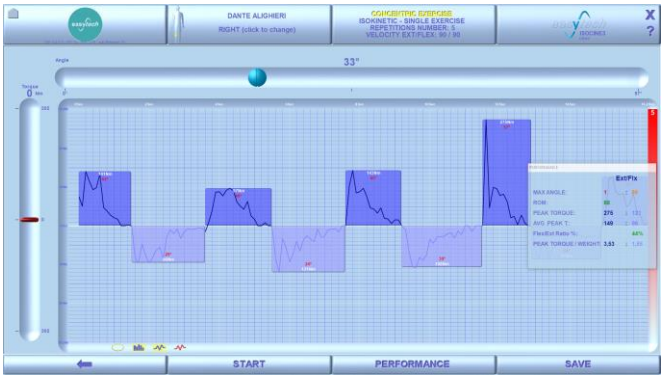
At the end of any dynamic exercise (isokinetic, hydrodynamic or isotonic), the program displays the following chart with the angle value in red and the torque value in blue. When the histogram is active, the program also displays the field with the preset torque range and the maximum torque value that corresponds to the relative angle.



By pressing the blue and/or red chart, it is possible to hide or display the trend of the torque and/or angle. If one or both charts are pressed once more, the program returns to the previous screen with 2 charts, while when the ellipsis button is pressed, the program displays the exercise with the angle and torque displayed on the X and Y axes, as shown in the following charts.



ANGLE/TIME CHART

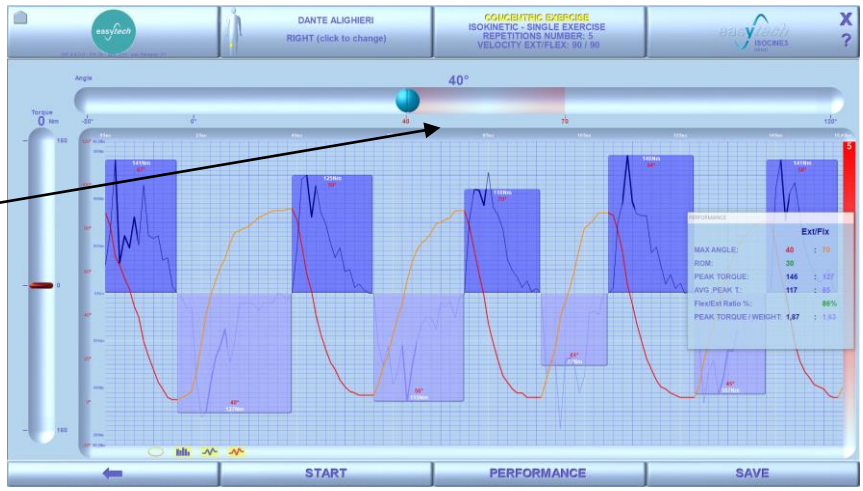


TORQUE/TIME CHART

TORQUE/ANGLE CHART

If the ACTIVE ROM limit is active (See figure below), only the field within the set limits will be processed.

ACTIVE ROM limit



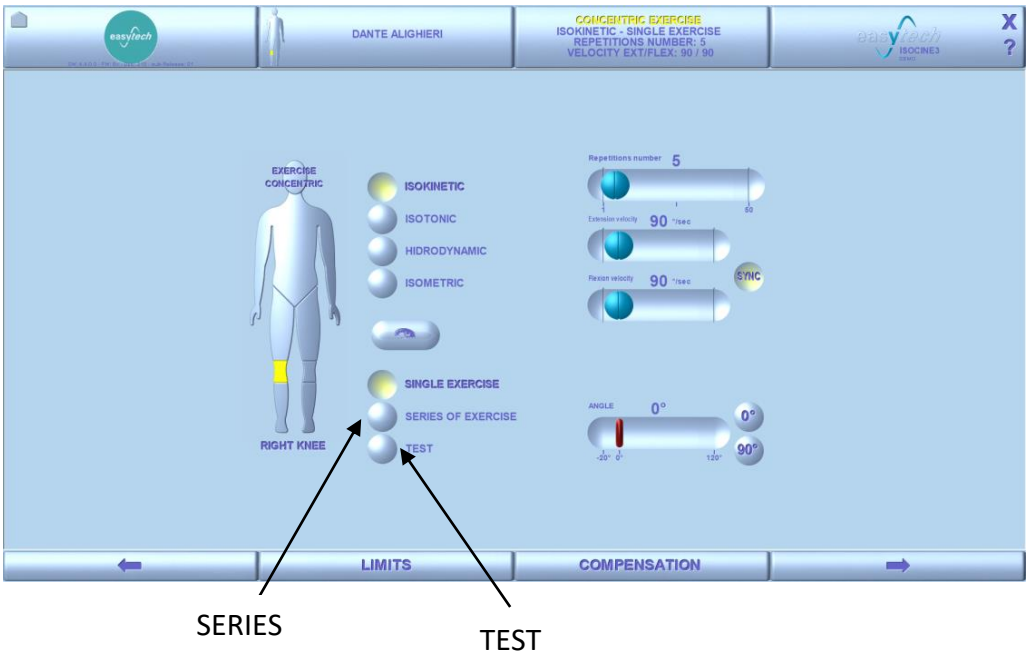
To print the report, the operator must save the exercise and access the archive. See paragraph 5.6.

5.3.1.6 Series of exercises and Isokinetic Test

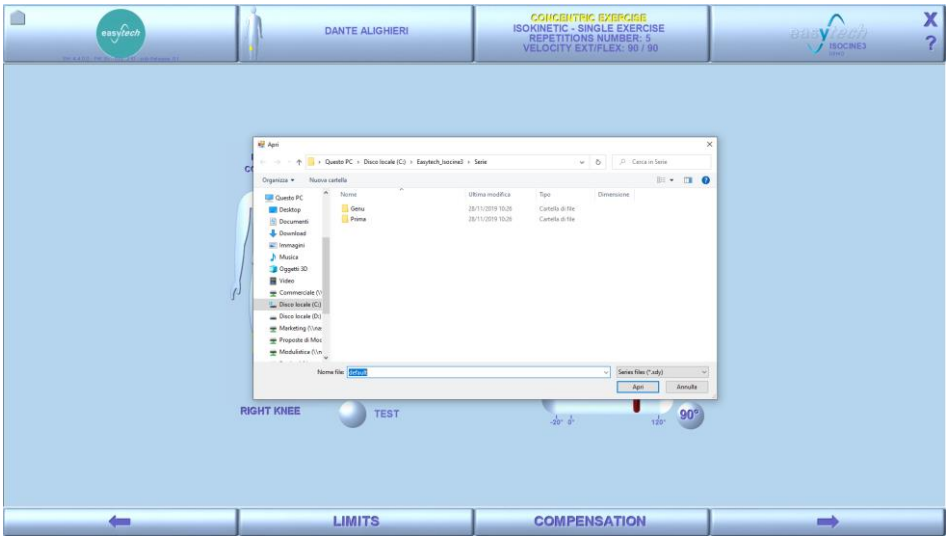
By pressing the SERIES button in the main window (See figure below), it is possible to recall a series of pre-established exercised, that is a working protocol compiled by the therapist (for more details see paragraph 5.7).

By pressing the TEST button in the main window, it is possible to load a series of pre-set exercises for the purpose of patient's health assessment.

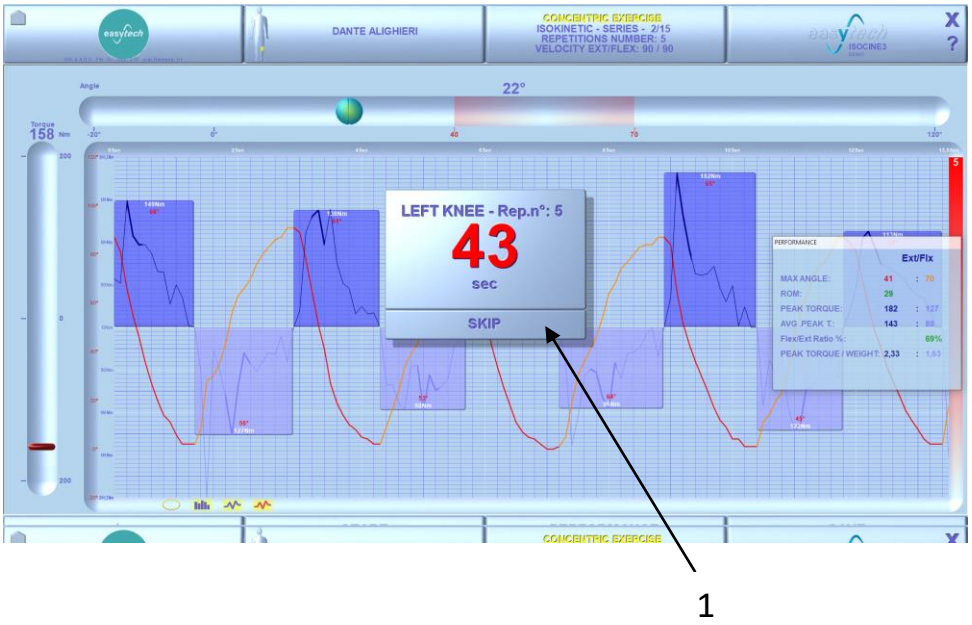
The operating procedures are identical at the beginning of any exercise: the limb, the type of motion and any limits must be identified and the exercise must be started by pressing the TEST or SERIES button.



The SERIES and TEST selection is identical: a navigator windows will open and the appropriate file can be selected. Confirm with OK.



The start of exercise is identical to the case of single exercise. At the end of each SERIES or TEST exercise, a waiting rest time window will appear.



1

Pressing button "1" allows the operator to immediately go to the next exercise, ignoring the rest time. At the end of SERIES or TEST the results obtained will be automatically saved.

5.3.2 Concentric isotonic exercise

5.3.2.1 Single exercise parameter settings

In the same way as we have seen for the isokinetic concentric exercise, it is necessary to set some parameters before starting the exercise.

In this case, the items that will be present on the screen are as follows:

Selection of the LIMB - Move the mouse over the figure of the human body and click the desired limb.

Setting the ANGLE – This phase is used to calibrate the encoder. Position the patient correctly (as instructions in section 4.3.1), attaching the lever to the ankle using the system provided. Fully extend the leg and press the 0° button to save the position. Eventually it is possible to do the same thing for 90° (bent leg). It is advisable to set the parameters when the leg is extended (0°), unless the therapist judges that it is impossible.

Number of repetitions – Move the cursor until the desired number displays and move the mouse to the right or left in increments of units for a fine adjustment.

Extension/flexion load - Set the desired value by moving the cursor. Move the cursor to the right or left in increments of units for a fine adjustment.

SYNCRO – The extension/flexion values will be the same.
The settings relating to the LIMITS and the COMPENSATION, as well as the analysis of graphics, the exercise SERIES and the TEST mode, are like the case of isokinetic exercise (see paragraph 5.3.1 and related sub-paragraphs).

5.3.3 Concentric hydrodynamic exercise

5.3.3.1 Single exercise parameter setting

In the same way as we have seen for the isokinetic concentric exercise, it is necessary to set some parameters before starting the exercise.

In this case, the items that will be present on the screen are as follows:

Selection of the LIMB - Move the mouse over the figure of the human body and click the desired limb.

Setting the ANGLE – This phase is used to calibrate the encoder. Position the patient correctly (as instructions in section 4.3.1), attaching the lever to the ankle using the system provided. Fully extend the leg and press the 0° button to save the position. Eventually it is possible to do the same thing for 90° (bent leg). It is advisable to set the parameters when the leg is extended (0°), unless the therapist judges that it is impossible.

Number of repetitions – Move the cursor until the desired number displays and move the mouse to the right or left in increments of units for a fine adjustment.

Extension/flexion Strenght - Set the desired value by moving the cursor. Move the cursor to the right or left in increments of units for a fine adjustment.

SYNCRO – The extension/flexion values will be the same.

The settings relating to the LIMITS and the COMPENSATION, as well as the analysis of graphics, the exercise SERIES and the TEST mode, are like the case of isokinetic exercise (see paragraph 5.3.1 and related sub-paragraphs).

5.3.4 Concentric isometric exercise

5.3.4.1 Single exercise parameter setting

In the same way as we have seen for the other concentric exercises, it is necessary to set some parameters before starting the exercise.

In this case, the items that will be present on the screen are as follows:

Selection of the LIMB - Move the mouse over the figure of the human body and click the desired limb.

Setting the ANGLE – This phase is used to calibrate the encoder. Position the patient correctly (as instructions in section 4.3.1), attaching the lever to the ankle using the system provided. Set the desired leg angulations, engage the mechanical lock on the front of the device body (see point 6 in the figure in paragraph 3.2), estimate/measure the leg flexion angle and set the value by pressing the corresponding virtual button or using the cursor.

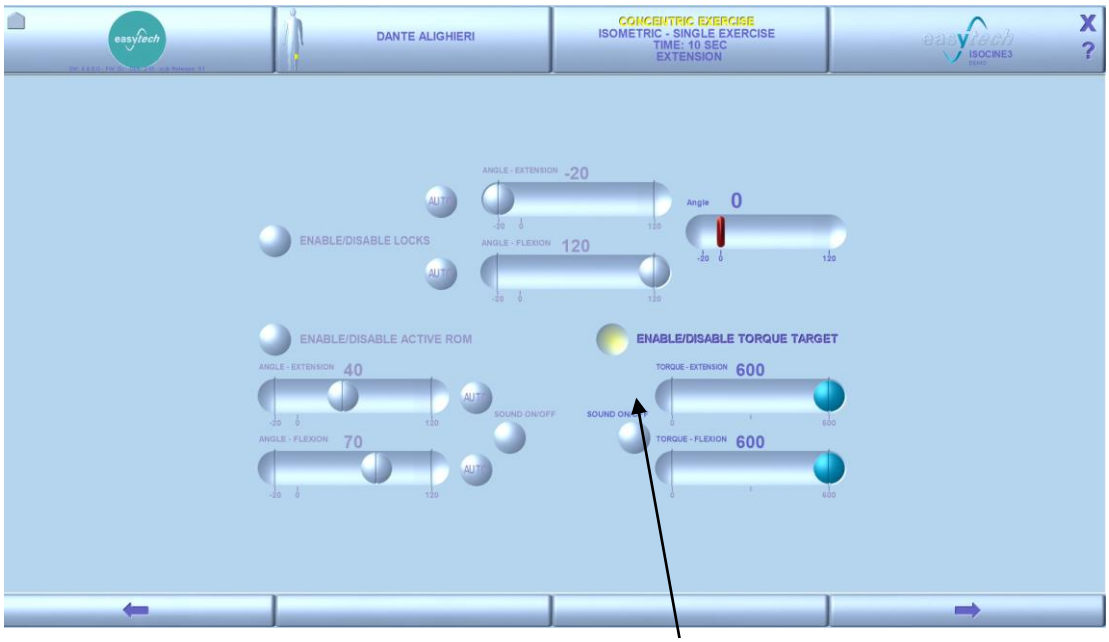
Time – Sets the duration time of each exercise. Move the cursor until the desired number displays and move the mouse to the right or left in increments of units for a fine adjustment.

Extension/flexion – Choose the type of movement.

Height of tibial support – Set the desired value by moving the cursor until the desired number displays and move the mouse to the right or left in increments of units for a fine adjustment.

In this type of exercise, it is possible to set only the LIMITS, while the COMPENSATION is not present.

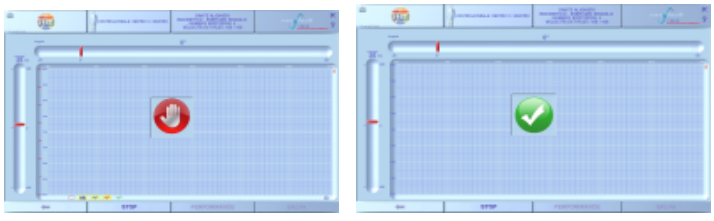
5.3.4.2 Setting the limits



1 – ENABLE/DISABLE TORQUE TARGET – If activated, a limit will be indicated on the graph during the exercise. This limit can be used by the patient as a target to be achieved; its default is the maximum value of the previous exercise.

5.3.4.3 Exercise in progress and review of graphics

Once all the settings have been completed, press the arrow at the bottom right to access the page relating to the exercise.
Press START, wait for the device to issue an acoustic/visual signal, then start the exercise.



Keep the set torque for the time expected from the exercise. The graph will show the progress of the exercise and the number of repetitions. At the end of the exercise the data can be saved (SAVE) and the maximum values reached will be displayed (PERFORMANCE) as show in the following figure.

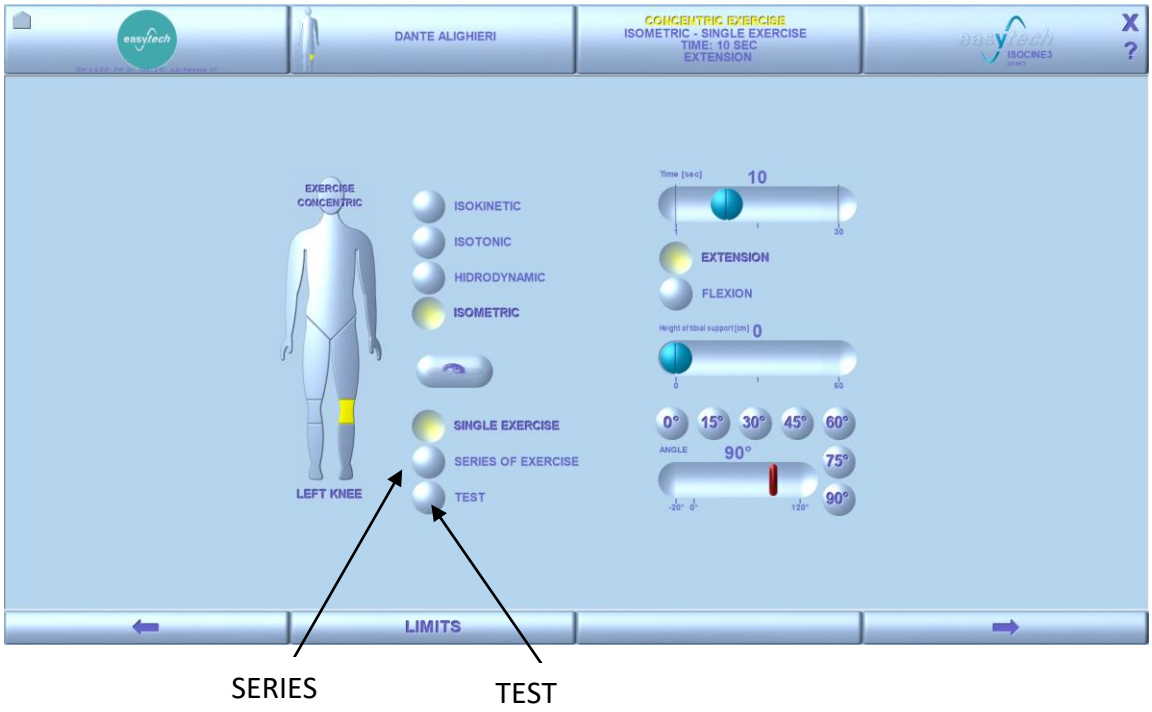
Rising Time – The two yellow and red indicators represent the limits used to calculate the time required to reach maximum fatigue. The yellow dot is the fixed lower limit above which the system starts calculating the time. The calculation stops as soon as the maximum value (red reference) is reached. The therapist may decide to move the maximum limit reached if the review of the outline indicates that the automatically detected point is not representative.

5.3.4.4 Series of exercises and Isometric Test

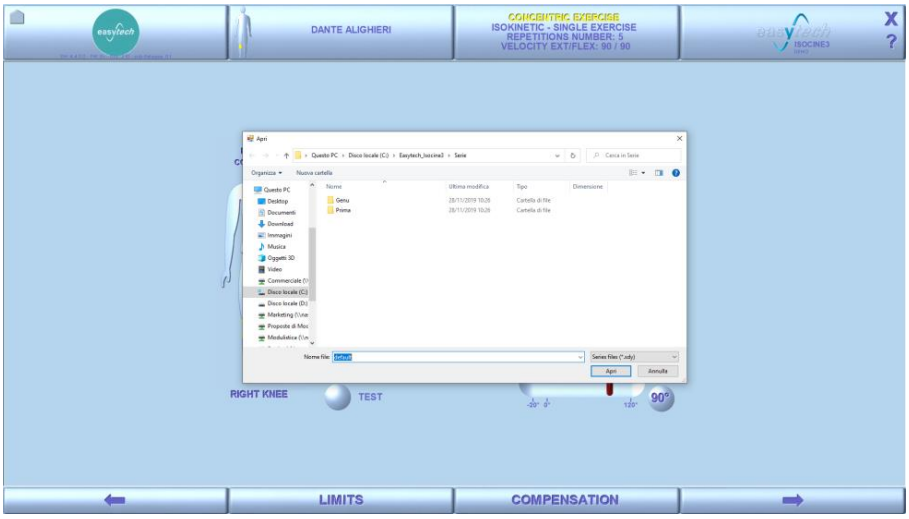
By pressing the SERIES button in the main window (See figure below), it is possible to recall a series of pre-established exercised, that is a working protocol compiled by the therapist (for more details see paragraph 5.7).

By pressing the TEST button in the main window, it is possible to load a series of pre-set exercises for the purpose of patient's health assessment.

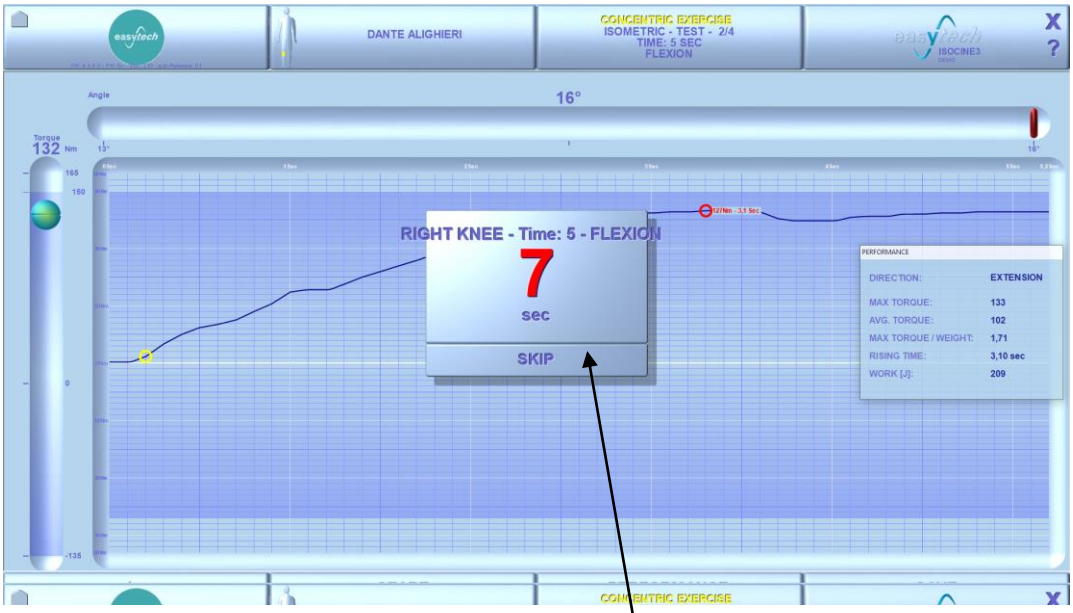
The operating procedures are identical at the beginning of any exercise: the limb, the type of motion and any limits must be identified and the exercise must be started by pressing the TEST or SERIES button.



The SERIES and TEST selection is identical: a navigator windows will open and the appropriate file can be selected. Confirm with OK.



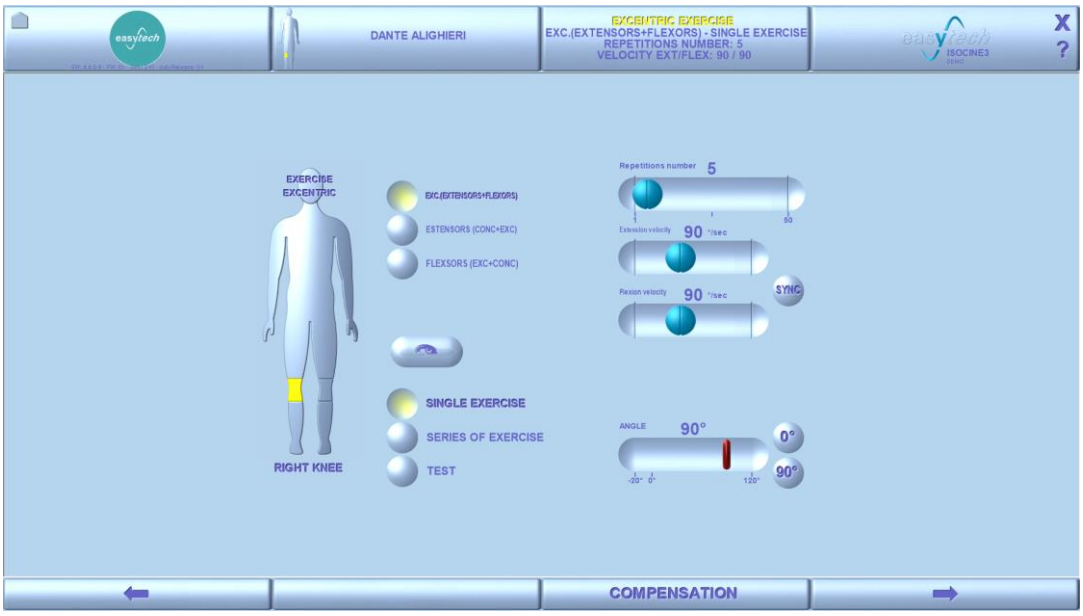
The start of exercise is identical to the case of single exercise. At the end of each SERIES or TEST exercise, a waiting rest time window will appear.



By pressing button 1, it is possible to immediately move to the following exercise ignoring the rest period.
At the end of the series or TEST, the obtained results are automatically saved.

5.4 ECCENTRIC EXERCISE

By selecting the “ECCENTRIC EXERCISE” from the main page, the following window will open:



In the opening screen of the page setting exercise has already identified the patient and the operator can choose, by pressing the virtual keys

- Type of Exercise (individual, series, test)
- Type of Motion (EXC-extensors+flexors, Extensors-CONC+EXC, Flexors EXC+CONC)
- Joint to be treated (GENU: Ginocchio)

There are 3 types of eccentric exercise:

- Pure eccentric exercise (symmetric) in which both the flexor muscles, and the extensors work in eccentric mode, respectively, in flexion and extension movements.
- Exercise only extensor muscles (asymmetric) in which the patient works with the extensor muscles during the extension movement (concentric) and continues to work with the extensor muscles during the flexion (eccentric)
- Exercise only flexor muscles (asymmetric) in which the patient works with the flexor muscles during the extension movement (eccentric) and continues to work with the flexor muscles during the flexion (concentric)

5.4.1 Single exercise parameter settings

The selection of the limb also involves the change in all the information appearing on the screen and on printouts and which are relative to the titles of the movements and the muscles involved. So if the selected limb is the knee it is called the flexion and extension.

SEGMENT	MUSCLES INVOLVED	MOVEMENTS
Knee	Flexors and extensors	Flexion / Extension

In the following, when we speak about a general movement (without specifying the limb) we will refer to the muscles and movements of the knee, so it is called flexion/extension.

Selection of the LIMB - Move the mouse over the figure of the human body and click the desired limb.

Setting the ANGLE – This phase is used to calibrate the encoder. Position the patient correctly (as instructions in section 4.3.1), attaching the lever to the ankle using the system provided. Fully extend the leg and press the 0° button to save the position. Eventually it is possible to do the same thing for 90° (bent leg). It is advisable to set the parameters when the leg is extended (0°), unless the therapist judges that it is impossible.

Number of repetitions – Move the cursor until the desired number displays and move the mouse to the right or left in increments of units for a fine adjustment.

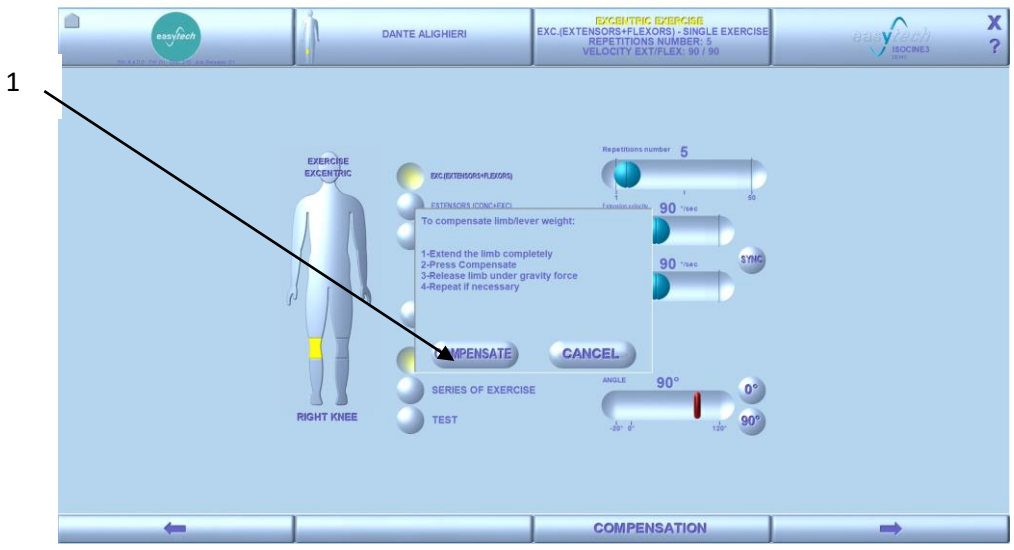
Extension/flexion speed - Set the desired value by moving the cursor. Move the cursor to the right or left in increments of units for a fine adjustment.

SYNCRO – The extension/flexion values will be the same.

To move to the next step, select COMPENSATION.

5.4.2 Gravity compensation

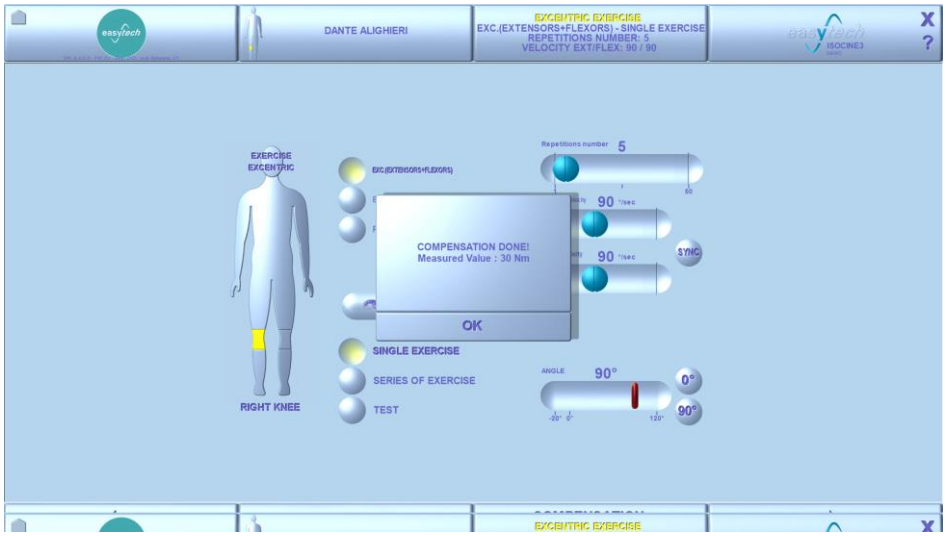
This operation compensates the weight of the lever and limb being treated and ensures that the results are accurate.
To access to the gravity compensation window from the limit settings screen, press the BACK arrow and thus return to the main screen of the concentric exercise. From here it is possible to access the COMPENSATION tab through the relative button. This will open the following window:



Position the patient following the instructions provided, extend the limb, press button 1 (COMPENSATE) and wait for the device to perform the compensation without forcing the operation (2 sec).

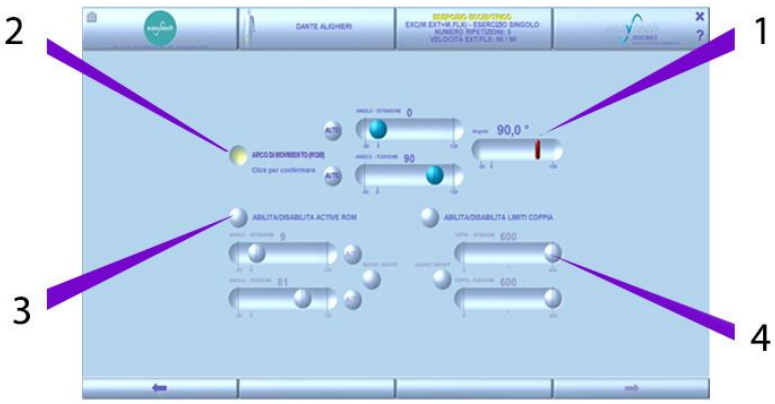
If the patient is the same, it is not necessary to repeat this operation at the beginning of each exercise, because the parameters are stored in the memory of the device. The therapist should compare the resulting value with the historical values to verify that the calibration is correct.

A confirmation screen will be displayed at the end of the operation:



5.4.3 Setting the limits

Clicking on the right arrow you proceed with the execution of the exercise, passing through the page of the range of motion setting (ROM).



1 – GONIOMETER THAT INDICATES THE ANGLE- check the correct indication

2 - SETTING THE RANGE OF MOTION (ROM) - Set the joint range. During the eccentric phase, the lever moves within the set range. Please be particularly careful in doing this, because the incorrect setting angles could result in serious damage to the articulation of the patient.
For the correct setting angles limit is necessary to set the correct angle of the limb:

- Bring the leg in flexion angle limit and press the Auto button next to the command setting the limiting flexion.
- Bring the leg angle limit extension and press the Auto button next to the command setting the limiting extension.

You can also set the angles through the sliders in the same manner just described for the setting of all the other parameters.

To continue with the exercise, you need to enable the range of motion (ROM) by clicking on the ball to the left of the command.

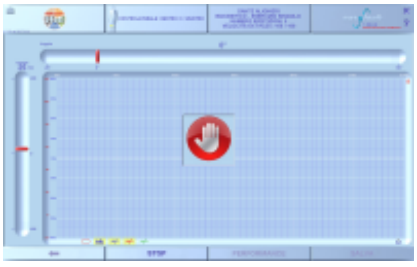
3 - ENABLE/DISABLE ACTIVE ROM (range of movement) – If enabled, it limits the range within which the exercises data will be processed. The default setting is 10% less than the arc of movement set with the key 2, to eliminate any artifacts generated by the inversion of motion (inversion of the direction of rotation of the motor)

4 - ENABLE/DISABLE TORQUE LIMIT – It will indicate on the chart during operation the maximum torque that can reach the patient. If the limit is enabled and the patient exceeds the set limit the exercise is stopped immediately.

Click on the arrow at the bottom right to continue with the exercise.

5.4.4 Exercise in progress

When the page opens press the START button wait beep / light from the system and start operation;

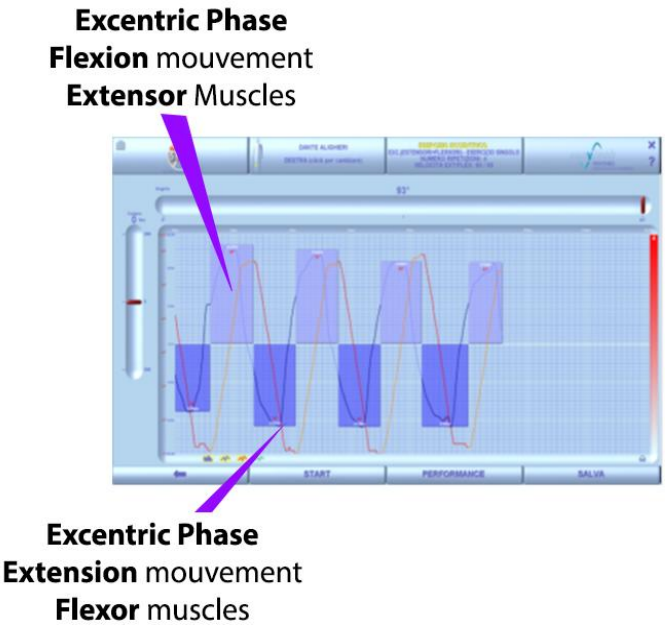


The exercise itself starts as soon as the patient makes the first move. During the exercise appear in real time the histograms of the maximum torque value (peak torque) of each movement.
Depending on the type of motion is set to have different results.

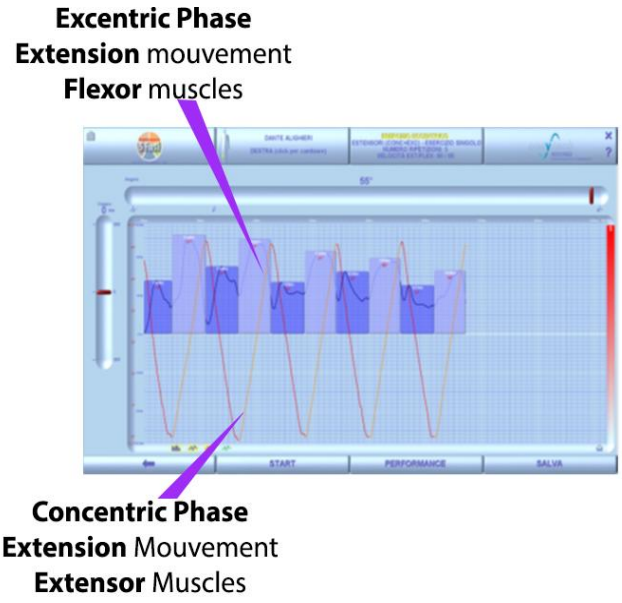
Please note the following rule:

- The torque of the **extensor** muscles is considered **Positive** and represented **above the zero axis** in the Cartesian diagram.
- The torque of **flexor** muscles is considered **Negative** and represented **below the axis of zero** in the Cartesian diagram.
- The movement of **extension** is represented with the color **Dark**
- The movement of **flexion** is represented with the color **Light**

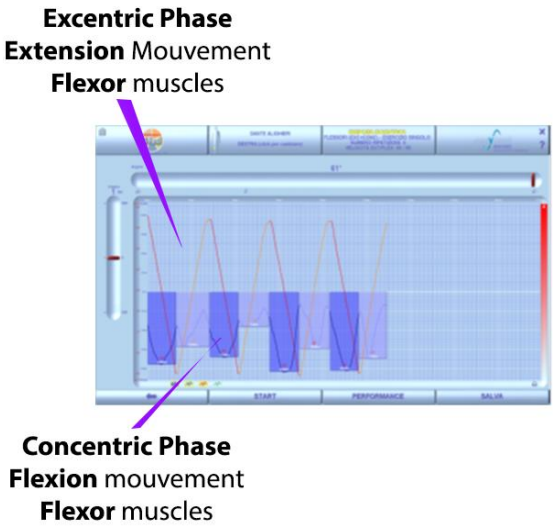
In the case **EXC - extensors + flexors** we have the following type of diagram:



In the case **Extensors - EXC + CONC** we have the following type of diagram:

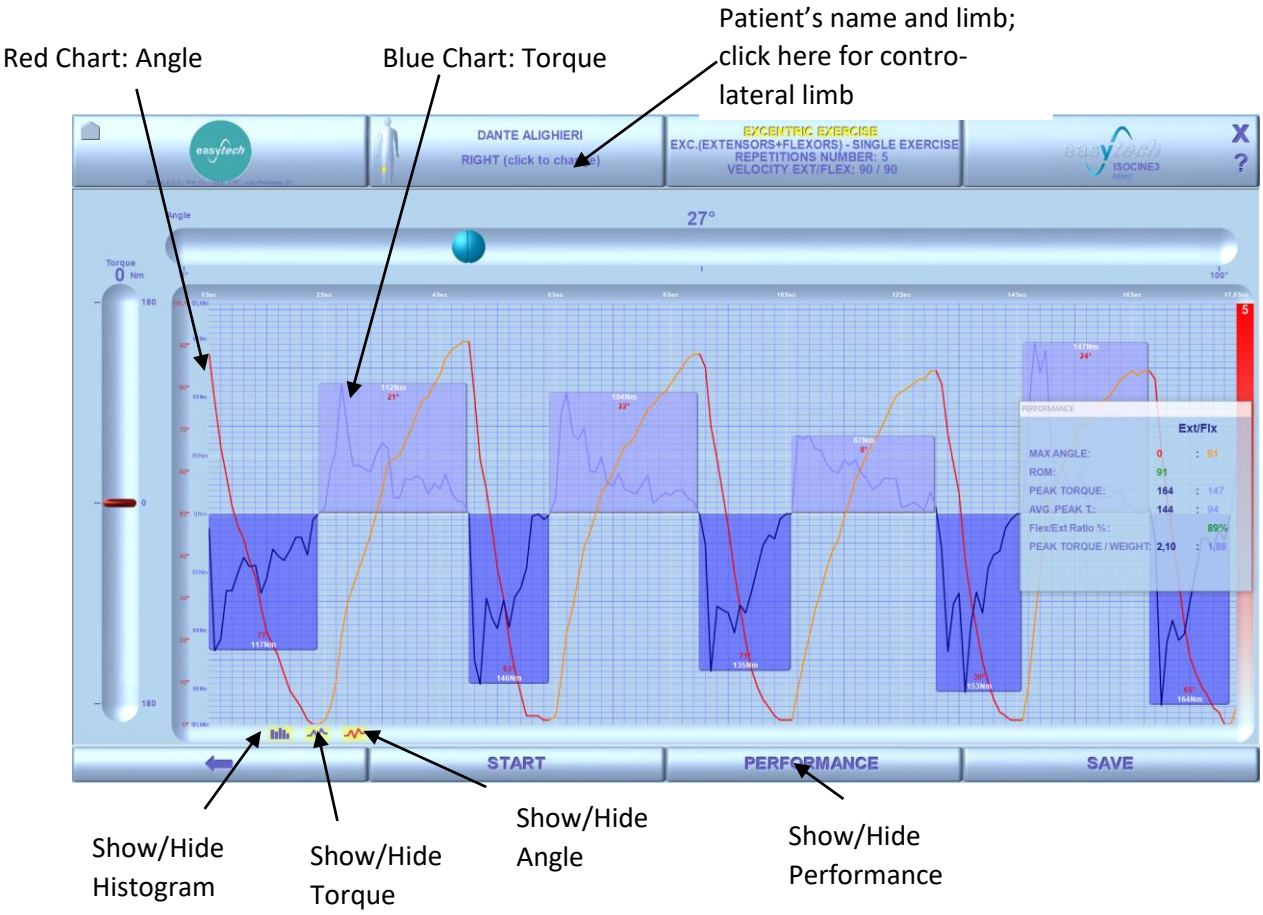


In the case flexors EXC + CONC we have the following type of diagram:



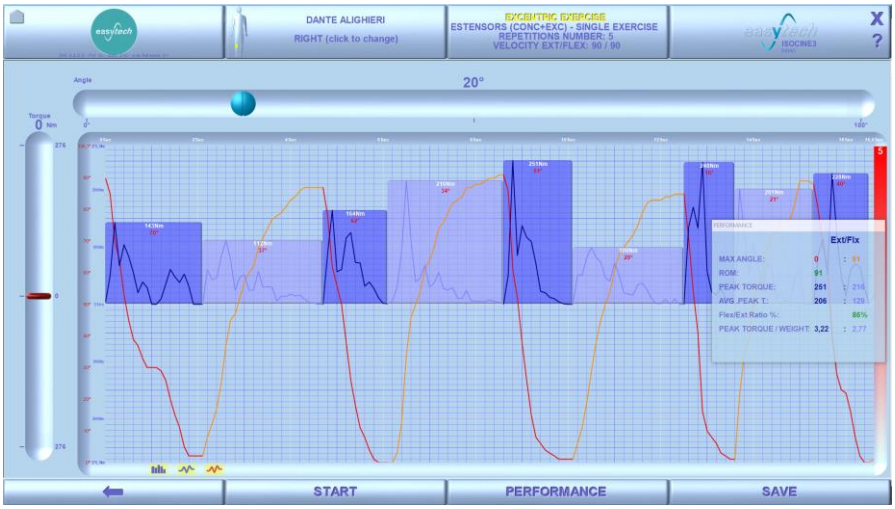
5.4.5 End of exercise and review of the graphics

At the end of an exercise appear the chart below with the angle value in red and the value of the torque in blue; with the histogram displays the active field of the torque limits preset and the maximum value of the torque with the 'relative angle.



Pressing the blue and or red diagram the torque / angle trend will disappear, by pressing it again it will return to the previous situation. All the commands and controls that can operate on the charts are similar to those described for the case of Concentric exercise (Section 5.3).

The above example is related to the case EXC - extensors + flexors, the CONC + EXC extensors and EXC + CONC flexors are similar and shown below.

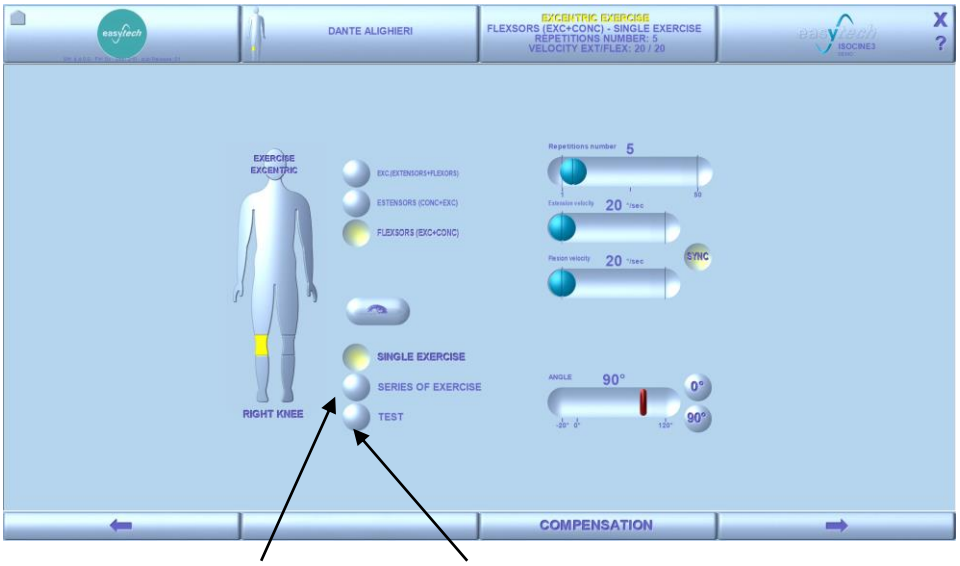


5.4.6 Series of exercises and Test

By pressing the SERIES button in the main window (See figure below), it is possible to recall a series of pre-established exercised, that is a working protocol compiled by the therapist (for more details see paragraph 5.7).

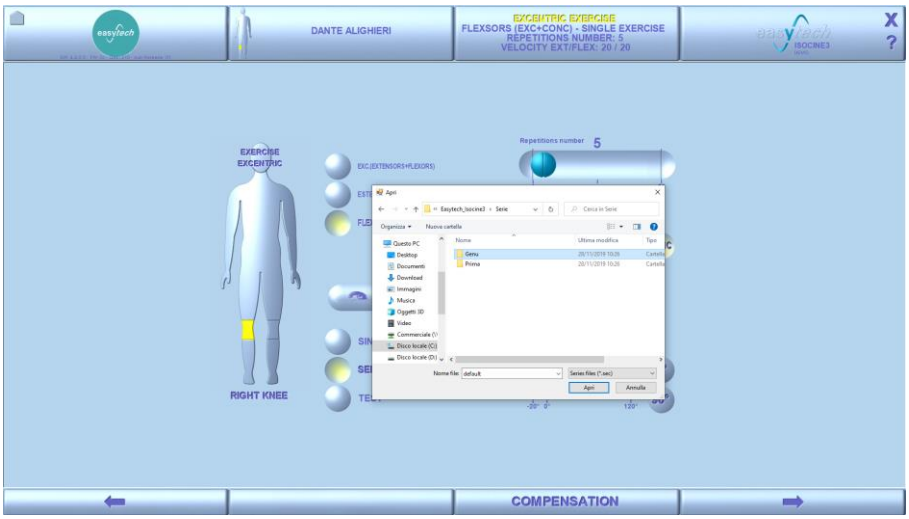
By pressing the TEST button in the main window, it is possible to load a series of pre-set exercises for the purpose of patient's health assessment.

The operating procedures are identical at the beginning of any exercise: the limb, the type of motion and any limits must be identified and the exercise must be started by pressing the TEST or SERIES button.



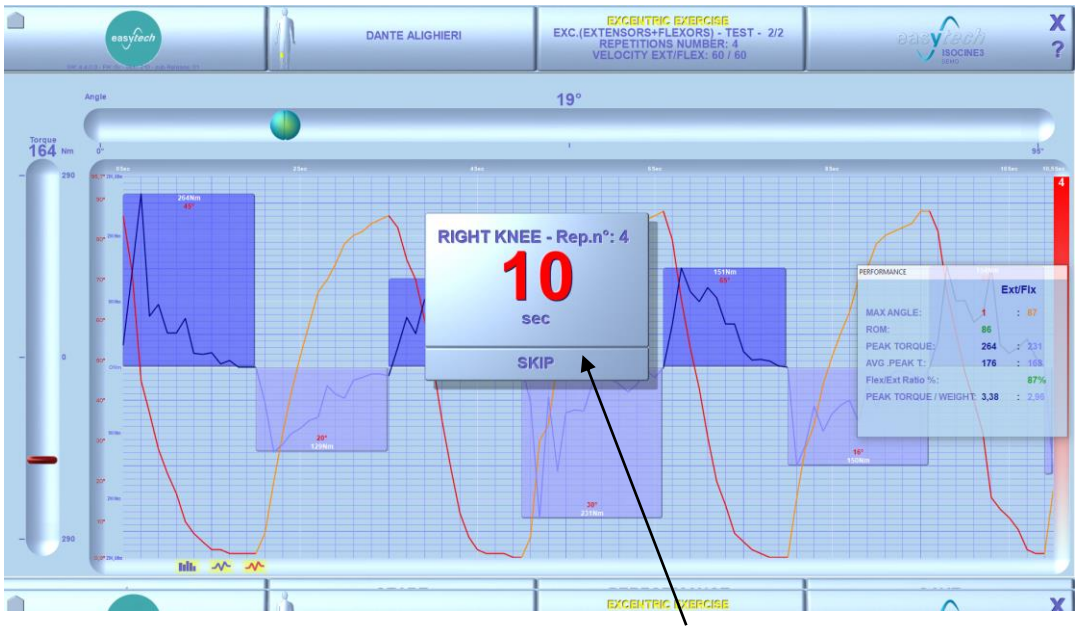
SERIES TEST

After selecting the SERIES or TEST as described above, the program opens a navigation screen where it is possible to select the desired file. Click OK to confirm.



The start procedure is the same as the one for single exercises.

At the end of each exercise of the SERIES or TEST, the program displays a screen with the rest time.

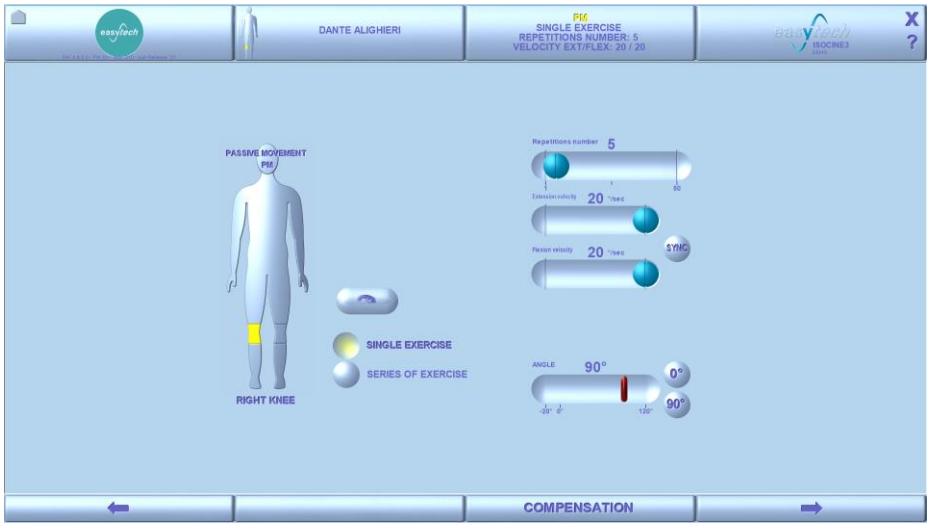


1

By pressing button 1, it is possible to immediately move to the following exercise ignoring the rest period.
At the end of the series or TEST, the obtained results can be saved with the appropriate button.

5.5 PASSIVE MOVEMENT EXERCISE (PM)

By selecting the “PASSIVE MOVEMENT (PM)” from the main page, the following window will open:



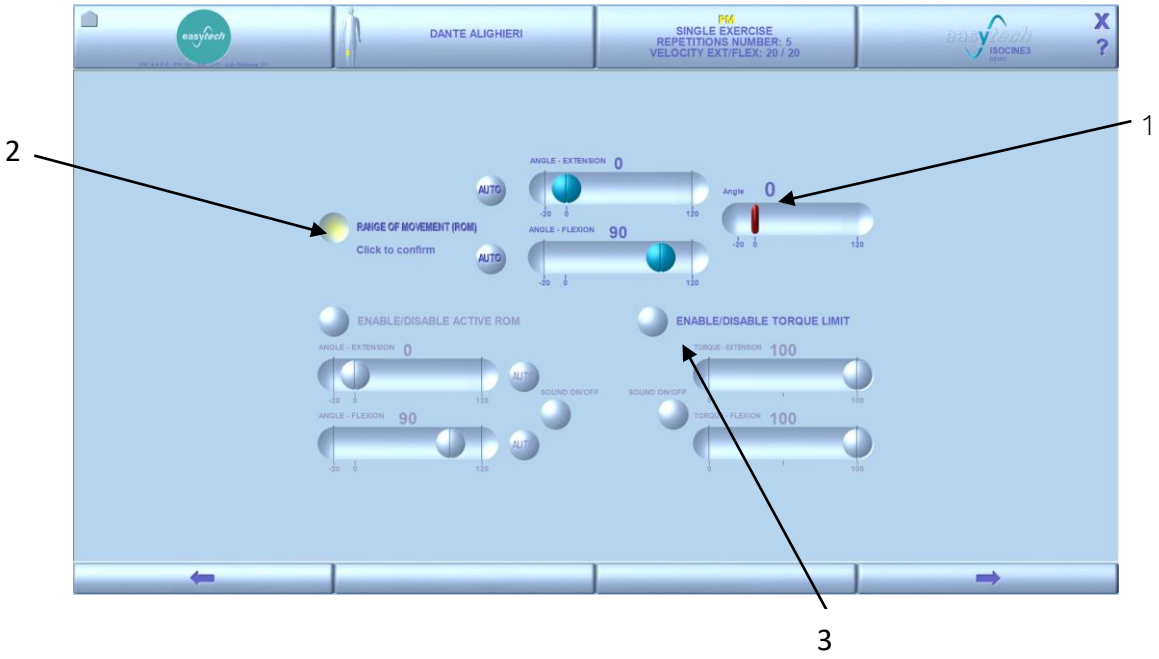
The selection screen of the parameters is similar to all others.
Only the adjustable range of angular speed will change - in this case 5°/s at 20°/s.

5.5.1 Gravity compensation

The compensation of gravity is identical to the other cases, during the Passive movement it serves only to set the torque limit function properly without taking account of the weight of the limb.

5.5.2 Setting the limits

Clicking on the right arrow you proceed with the execution of the exercise, passing through the page of the range of motion setting (ROM).



1 – GONIOMETER THAT INDICATES THE ANGLE- check the correct indication

2 - SETTING THE RANGE OF MOTION (ROM) - Set the joint range. During the eccentric phase, the lever moves within the set range. Please be particularly careful in doing this, because the incorrect setting angles could result in serious damage to the articulation of the patient.
For the correct setting angles limit is necessary to set the correct angle of the limb:

- Bring the leg in flexion angle limit and press the Auto button next to the command setting the limiting flexion.
- Bring the leg angle limit extension and press the Auto button next to the command setting the limiting extension.

You can also set the angles through the sliders in the same manner just described for the setting of all the other parameters.

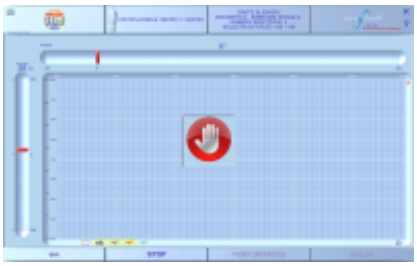
To continue with the exercise, you need to enable the range of motion (ROM) by clicking on the ball to the left of the command.

3 - ENABLE/DISABLE TORQUE LIMIT – It will indicate on the chart during operation the maximum torque that can reach the patient. Its default is the maximum value of the previous exercise.

Click on the arrow at the bottom right to continue with the exercise.

5.5.3 Exercise in progress

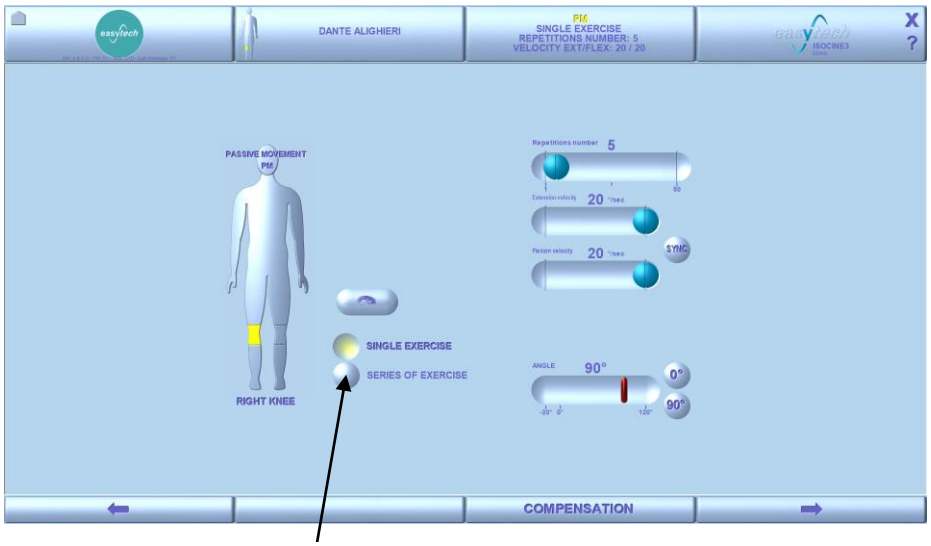
When the page opens press the START button wait beep / light from the system and start operation;



The exercise itself starts as soon as the patient makes the first move. The exercise time is display during the exercise.
After the repetitions are over, the time taken will remain on the screen. Is now possible to save the exercise.

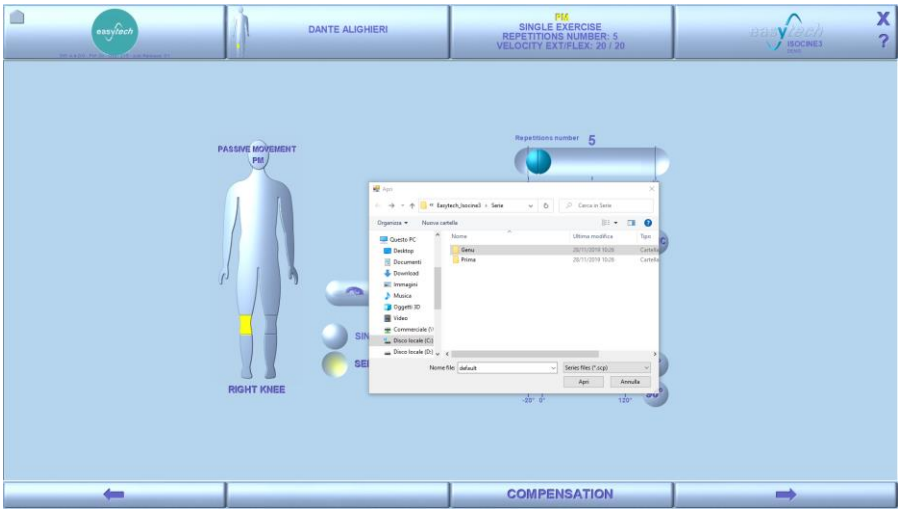
5.5.4 Series of exercises and Test

By pressing the SERIES button in the main window (See figure below), it is possible to recall a series of pre-established exercised, that is a working protocol compiled by the therapist (for more details see paragraph 5.7).



SERIES

After selecting the SERIES as described above, the program opens a navigation screen where it is possible to select the desired file. Click OK to confirm.



5.6 MANAGEMENT OF DATABASES

5.6.1 Selection of a patient

Select menu item “Patient” from the main screen in order to access the functions for the selection, entry and modification of patients. Select the patient and then return to the main screen and select section "Databases”.

5.6.2 Sessions table

The menu item “Archive” in the main screen gives access to all the database review functions.

The first access page is shown in the following figure. It displays the tables of all the exercises performed by the selected patient and with a specific limb.
Each column represents an exercise, while the rows contain the fields with the stored data.

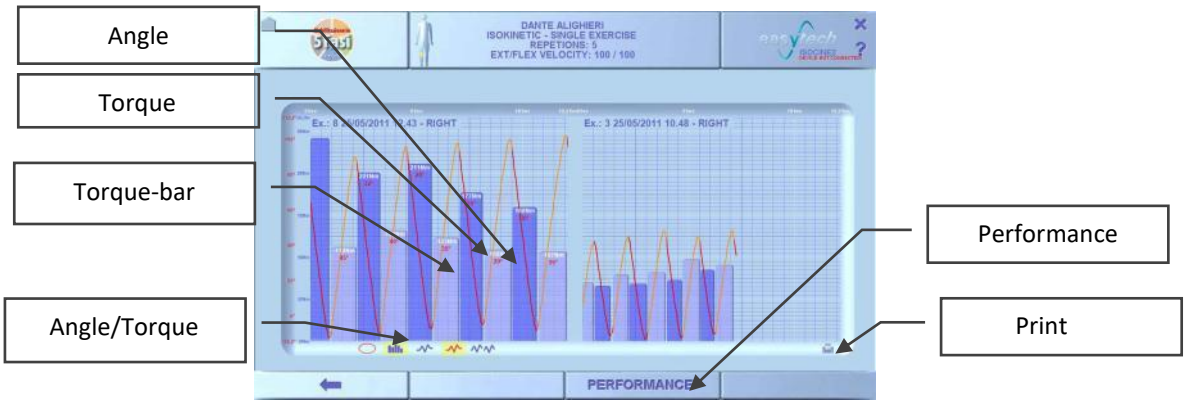
Highlight with the cursor the exercise/exercises you wish to review and press button "Display selected exercises".
To display the exercises that are not visible on the page, scroll the images down.
If only one exercise is selected, the chart display button leads to the same chart display windows that is proposed at the end of each exercise or test, with the same possibilities for viewing, consulting, writing/reading reports. For a more detailed description, refer to the previous paragraph.
The procedure and the available options are the same if 2 exercises are selected. The difference in this case is that it is possible to compare two exercises performed at different times (to determine the evolution of the trauma) or related to two limbs (the limb being examined and the contralateral limb). The display scale is obviously smaller, but the options are the same.

From this window the operator can also print the report of the exercise or exercises.

5.6.3 Analysis and comparison of the outlines

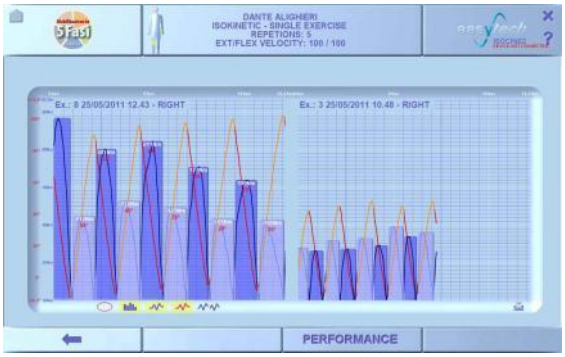
Comparative chart of two isokinetic sessions

Time on the X-axis and angle and torque on the Y-axis



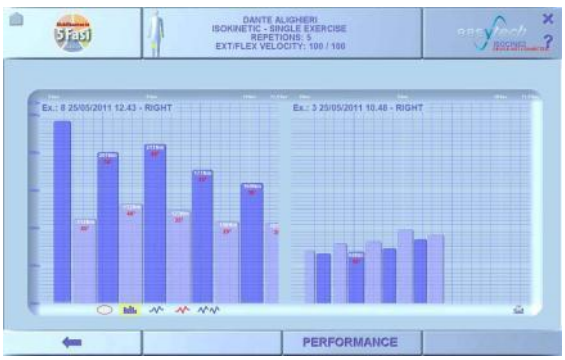
Angle/time chart of the two exercises

Image obtained by pressing the blue chart

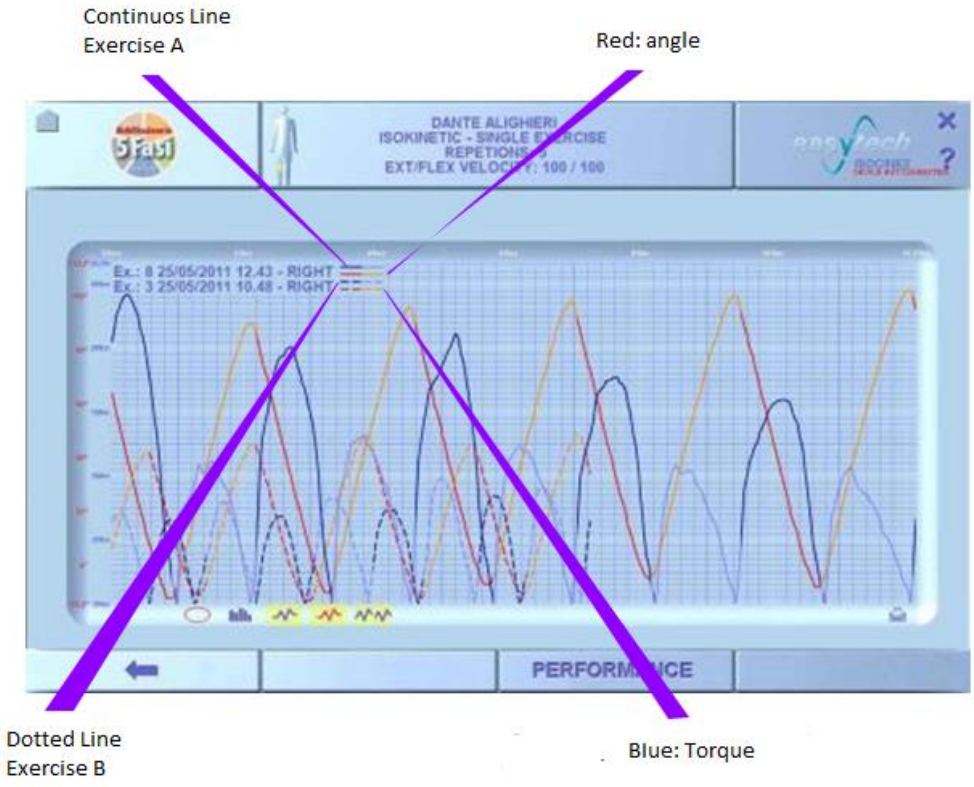


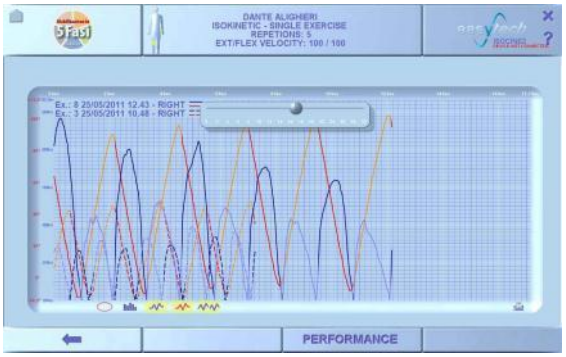
Torque/time chart of the two exercises

Image obtained by pressing the red chart

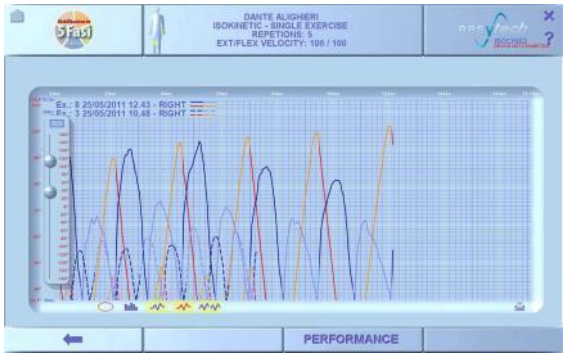


Display of two overlapped exercises
Image obtained by pressing button 1 on the double chart 1



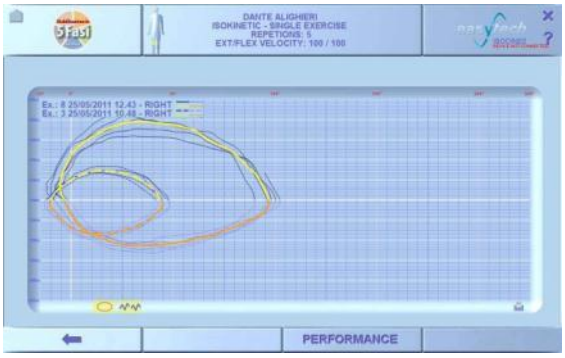


Display of the two overlapped exercises with X axis changed

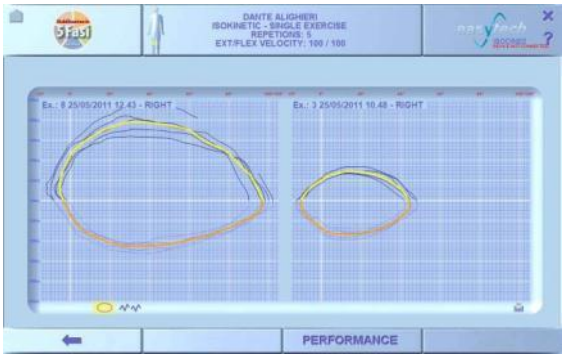


Display of two overlapped exercises with Y axis changed

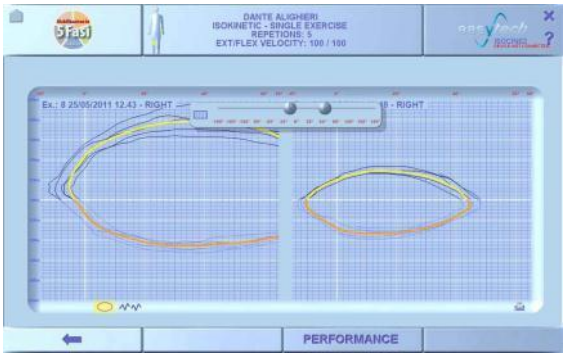
Display with angles on the X axis and torque on the Y axis



Angle and torque of all the repetitions of the 2 overlapped exercises

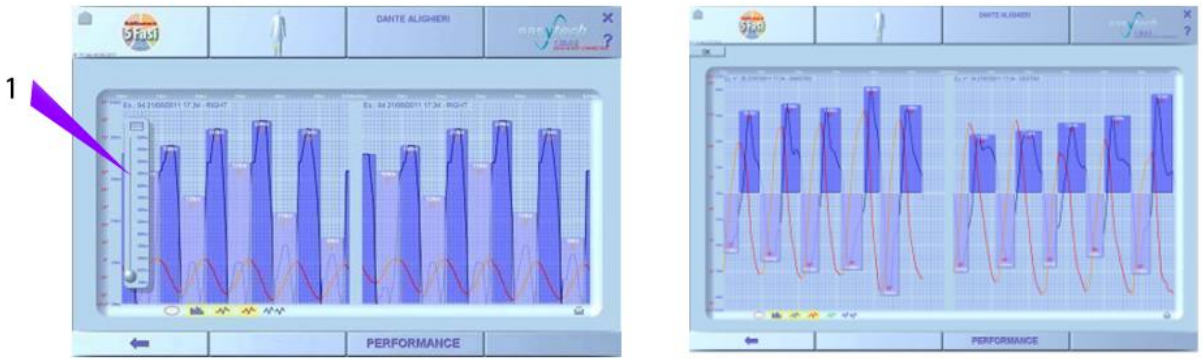


Angle and torque of all the repetitions of 2 different exercises

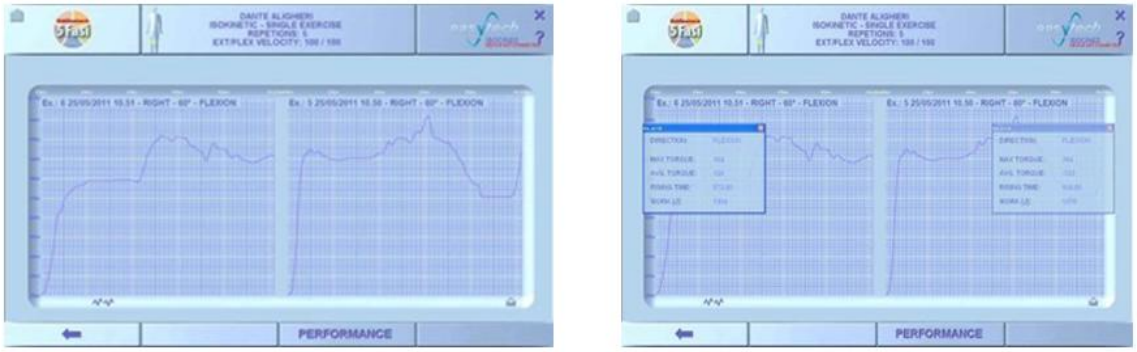


Angle and torque of all the repetitions of the 2 different exercises displayed with a different scale

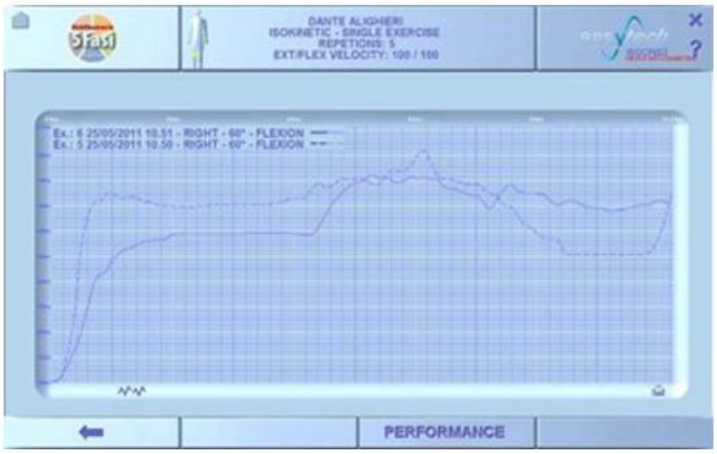
By clicking the torque scale, it is possible to change the scale and select a value with sign instead of an absolute value by clicking box 1. above the slider for the torque scale adjustment.



Comparative chart of two isometric sessions



Comparative chart of the flexion exercises / Whith performance higtlighted



Charts of overlapped exercises
Time on the X-axis and torque on the Y-axis

In all the database pages, it is always possible to highlight a point of the chart with the mouse in
order to display the performance value referred to the selected point.
It is always possible to print the displayed page.

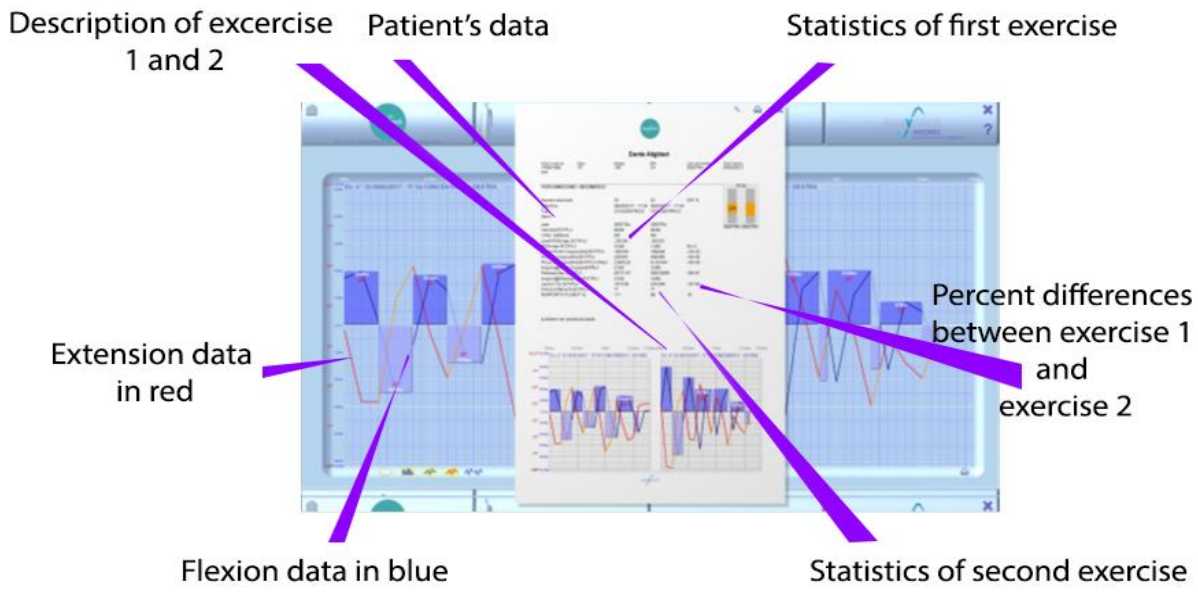
The settings and interfacing options are the same as those of other working modes (hydrodynamic, isotonic). The only exception is that different parameters are displayed: viscosity for the hydrodynamic mode and load for the isotonic mode. In the isometric mode, the shape of the chart is slightly different.

5.6.4 Tables printouts

In each archive window there is the print button (in the bottom right of the screen).

Clicking on this icon will open the report of the exercise or exercises. In this report there is a comparative table which contains the data of the two selected exercises and in which are highlighted the different between them.

The following figure shows an example of table printout.


Description of excercise 1 and 2
Patient's data
Statistics of first exercise
Percent differences between exercise 1 and exercise 2
Extension data in red
Flexion data in blue
Statistics of second exercise

By clicking on the report print icon, the operator can select the type of printer and start the printing process.

5.6.4.1 Isokinetic test report

An isokinetic test generally includes two exercises:

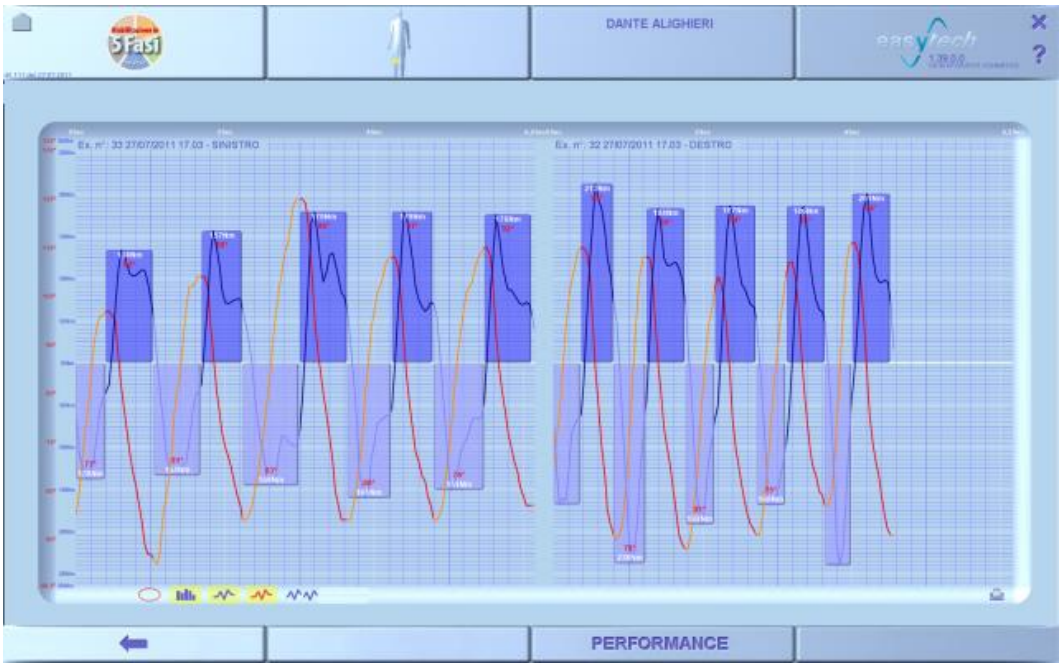
- A first exercise on the healthy limb
- A second exercise on the sick limb

There are several types of isokinetic tests:

- Force test – Example: 4 repetitions at 90 degrees/second
- Resistance test – Example: 20 repetitions at 180 degrees/second

It is necessary to perform two exercises in sequence by setting them manually or loading a pre-programmed test through the appropriate control.

It is then possible to select from Database two exercises, analyses and print the report.



The isokinetic test screen is that same that will be displayed when two random exercises are loaded and when the time and amplitude scale adjustment controls are used.
The exercise displayed on the left refers to the limb being examined.
The exercise displayed on the right refers to the reference contralateral limb.
The icons in the lower left enables to change the type of display, as follows:

Toggles the display with the time on the X axis and the angle on the Y axis

Displays/hides the charts

Displays/hides the torque curve

Displays/hides the angle curve

Toggles the display with overlapped exercises and two separate exercises

The printer icon in the lower left side enables to print the report containing the numerical data along with the currently displayed charts.

The columns of the following example of report represent:

1. Exercise performed with the sick limb being examined
2. Exercise performed with the reference contralateral limb
3. Percentage differences between the sick and contralateral limbs
4. Ratio between the values of the sick and contralateral limbs

Dante Alighieri

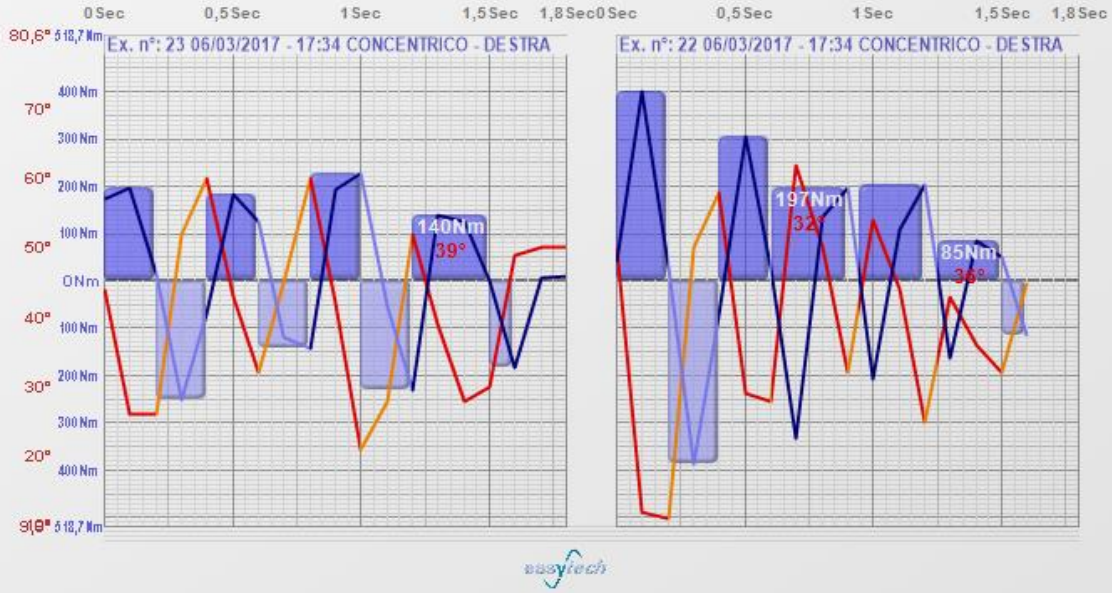
Data di nascita	Peso	Altezza	BMI	Lato dominante	Data trauma
14/06/1955	78	180	24	DESTRA	04/02/2012
SSN					

TEST:GINOCCHIO - ISOCINETICO

ROM

Numero esercizio	23	22	Diff. %
Data/Ora	06/03/2017 - 17:34	06/03/2017 - 17:34	
Tipo	CONCENTRICO	CONCENTRICO	
Serie			
Lato	DESTRA	DESTRA	
Velocità EXT/FLX	90/90	90/90	
n.Rip. Set/Exec.	5/5	5/5	
Limiti ROM Imp. EXT/FLX	-20/120	-20/120	
ROM max EXT/FLX	21/60	11/62	91/-3
Media Picchi Coppia [Nm] EXT/FLX	150/160	196/240	-23/-33
Picco di coppia [Nm] EXT/FLX	226/251	399/385	-43/-35
Picco di coppia [Nm] EXT/FLX / Peso	2,90/3,22	5,12/4,94	-43/-35
Angolo@Picco Coppia EXT/FLX	21/52	12/50	
Potenza Max EXT/FLX	827/1147	2651/2659	-69/-57
Angolo@Potenza Max EXT/FLX	21/52	12/50	
Lavoro Tot. EXT/FLX	151/136	241/249	-37/-45
Indice di fatica % EXT/FLX	*/*	*/*	
RAPPORTO FLX/EXT %:	111	96	16

problemi vari cadute acciacchi



5.6.4.2 Eccentric Isokinetic Test Report

The report of the test in case of eccentric exercise is very similar to the case described in the preceding paragraph, relating only to concentric exercises.
Establish first of all a terminology made of acronyms which, for reasons of space, must be used in the program.

- CNC = CONCENTRIC Identifies a pure **concentric exercise** (flexion and extension)
- EXC = ECCENTRIC Identifies a **pure eccentric exercise** (flexion and extension)
- M.Ext = **extensor muscles** Identify an exercise that involves only the **extensors muscles** (Concentric+ Eccentric).
- M.Flx = **flexor muscles** Identifies an exercise that involves only the **flexors muscles** (Concentric Eccentric +).
- EXT = EXTENSION Identifies the **extension phase** of an exercise (concentric or eccentric)
- FLX = FLEXION Identifies the **flexion phase** of an exercise (concentric or eccentric)
- MEC = **Concentric extensors muscles** Identifies the extension phase with **Concentric activation of extensors muscles.**
- MFC = **Concentric Flexors Muscles** Identifies the flexion phase with **Concentric activation of flexors muscle.**
- MEE = **Eccentric extensors Muscles** Identifies the phase of flexion with **eccentric activation of extensors muscles.**
- MFE = **Eccentric flexors Muscles** Identifies the extension phase **with Eccentric activation of flexors muscle.**

The operating conditions include the following cases:

- **Pure Concentric Exercise (CNC) in Extension (EXT)** work the extensors muscles **(MEC)** and flexion **(FLX)** work the flexors muscles **(MFC).**
- **Pure eccentric exercise (EXC):** in Extension **(EXT)** work the flexors muscles **(MFE)**and flexion **(FLX)** work the extensors muscles **(MEE).**
- **Exercise muscles extensors (M.Ext)**: always working the **muscles extensors. Concentric during the extension (MEC) and Eccentric during flection (MEE).**
- **Exercise muscles flexors (M.Flx)**: always working the **muscles flexors Eccentric during the extension (MFE) and Concentric during the phase of flexion (MFC).**

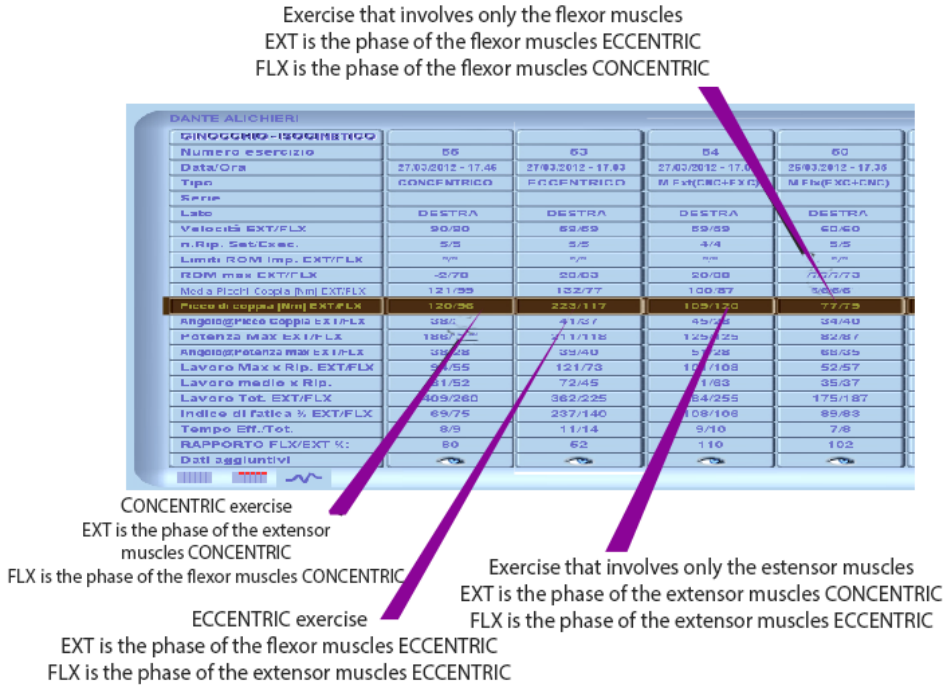
The exercises saved (stored) are all presented in a single table so you can select different types of exercises and to compare the performance of agonist and antagonist muscles (flexors and extensors when the knee) in different operating conditions (Concentric and eccentric).

The table below shows what the results in the case of selecting two exercises each homogeneous or inhomogeneous.
The columns represent the first exercise done in order of time, namely that relating to the muscles that you want to consider as a reference.
The lines represent the second exercise done in order of time, namely that relating to the muscles you want to analyze.

Legend

	CNC-1	EXC-1	M.Ext-1	M.Flx-1
CNC-2	EXT-1=MEC-1 EXT-2=MEC-2 FLX-1=MFC-1 FLX-2=MFC-2	EXT-1=MFE-1 EXT-2=MEC-2 FLX-1=MEE-1 FLX-2=MFC-2	EXT-1=MEC-1 EXT-2=MEC-2 FLX-1=MEE-1 FLX-2=MFC-2	EXT-1=MFE-1 EXT-2=MEC-2 FLX-1=MFC-1 FLX-2=MFC-2
EXC-2	EXT-1=MEC-1 EXT-2=MFE-2 FLX-1=MFC-1 FLX-2=MEE-2	EXT-1=MFE-1 EXT-2=MFE-2 FLX-1=MEE-1 FLX-2=MEE-2	EXT-1=MEC-1 EXT-2=MFE-2 FLX-1=MEE-1 FLX-2=MEE-2	EXT-1=MFE-1 EXT-2=MFE-2 FLX-1=MFC-1 FLX-2=MEE-2
M.Ext-2	EXT-1=MEC-1 EXT-2=MEC-2 FLX-1=MFC-1 FLX-2=MEE-2	EXT-1=MFE-1 EXT-2=MEC-2 FLX-1=MEE-1 FLX-2=MEE-2	EXT-1=MEC-1 EXT-2=MEC-2 FLX-1=MEE-1 FLX-2=MEE-2	EXT-1=MFE-1 EXT-2=MEC-2 FLX-1=MFC-1 FLX-2=MEE-2
M.Flx-2	EXT-1=MEC-1 EXT-2=MFE-2 FLX-1=MFC-1 FLX-2=MFC-2	EXT-1=MFE-1 EXT-2=MFE-2 FLX-1=MEE-1 FLX-2=MFC-2	EXT-1=MEC-1 EXT-2=MFE-2 FLX-1=MEE-1 FLX-2=MFC-2	EXT-1=MFE-1 EXT-2=MFE-2 FLX-1=MFC-1 FLX-2=MFC-2

This legend is used to correctly interpret the values outlined in the tables and reports. By way of example, see the highlighted line on the peak torque.


Exercise that involves only the flexor muscles
EXT is the phase of the flexor muscles ECCENTRIC
FLX is the phase of the flexor muscles CONCENTRIC
DANTE ALICHIERI
Numero esercizio
Data/Ora
Tipo
Serie
Lato
Velocità EXT/FLX
n.Rip. Set/Exec.
Limiti ROM Imp. EXT/FLX
ROM max EXT/FLX
Media Picchi Coppia [Nm] EXT/FLX
Picco di coppia [Nm] EXT/FLX
Angolo@Picco Coppia EXT/FLX
Potenza Max EXT/FLX
Angolo@Potenza Max EXT/FLX
Lavoro Max x Rip. EXT/FLX
Lavoro medio x Rip.
Lavoro Tot. EXT/FLX
Indice di fatica % EXT/FLX
Tempo Eff./Tot.
RAPPORTO FLX/EXT %:
Dati aggiuntivi
DESTRA
120/36
223/117
105/120
77/75
CONCENTRIC exercise
EXT is the phase of the extensor muscles CONCENTRIC
FLX is the phase of the flexor muscles CONCENTRIC
ECCENTRIC exercise
EXT is the phase of the flexor muscles ECCENTRIC
FLX is the phase of the extensor muscles ECCENTRIC
Exercise that involves only the estensor muscles
EXT is the phase of the extensor muscles CONCENTRIC
FLX is the phase of the extensor muscles ECCENTRIC

Regarding the last line, the one named REPORT FLX / EXT:

Exercise CONCENTRIC: FLX / EXT = CONCENTRIC FLEXOR / CONCENTRIC EXTENSOR

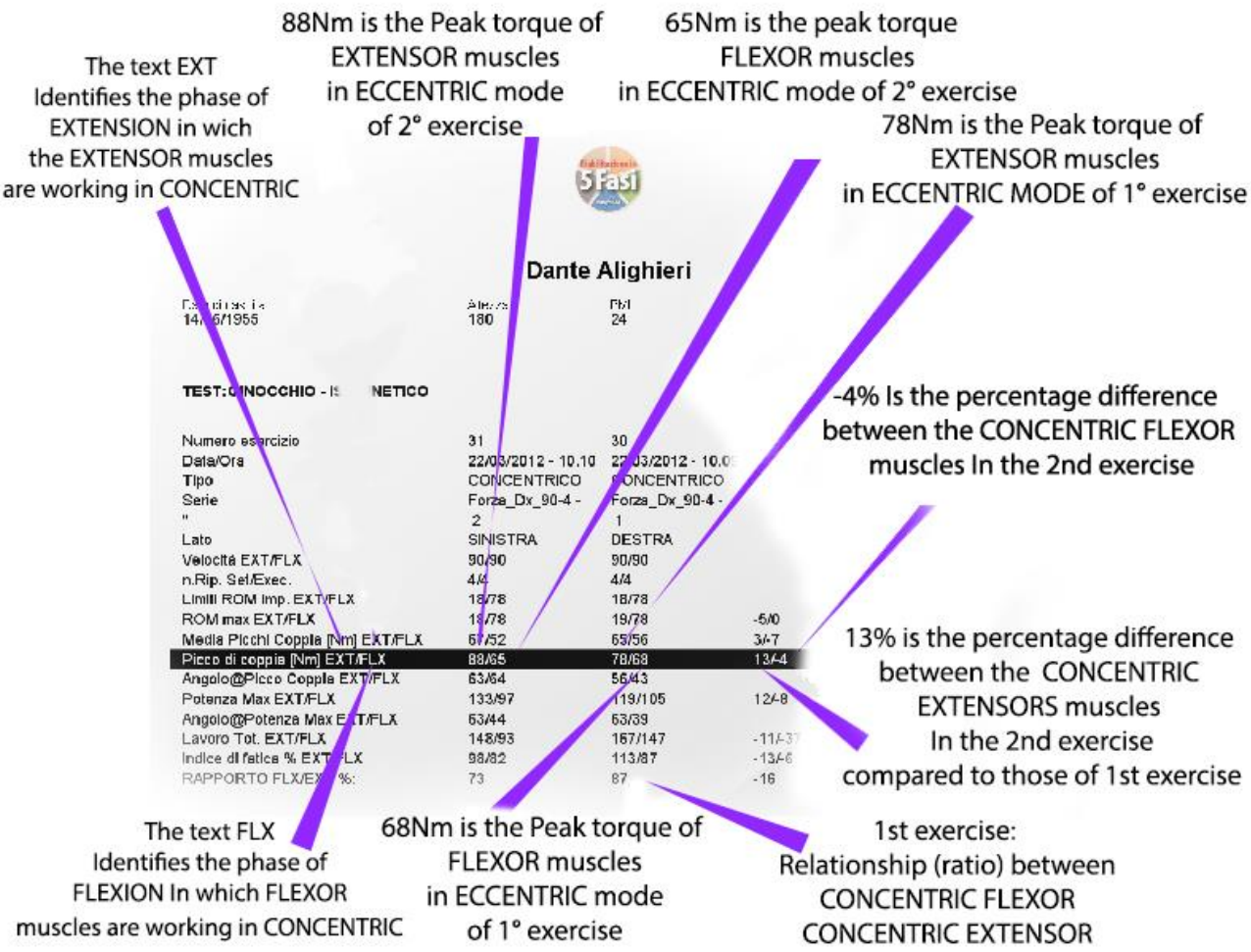
Exercise ECCENTRIC: FLX / EXT = ECCENTRIC EXTENSORS / ECCENTRIC FLEXOR

Exercise extensor muscles: FLX / EXT = ECCENTRIC EXTENSORS / CONCENTRIC EXTENSORS

Exercise flexors: FLX / EXT = CONCENTRIC FLEXORS / ECCENTRIC FLEXOR

Note the following example on a test composed of 2 exercises Isokinetic Concentric.

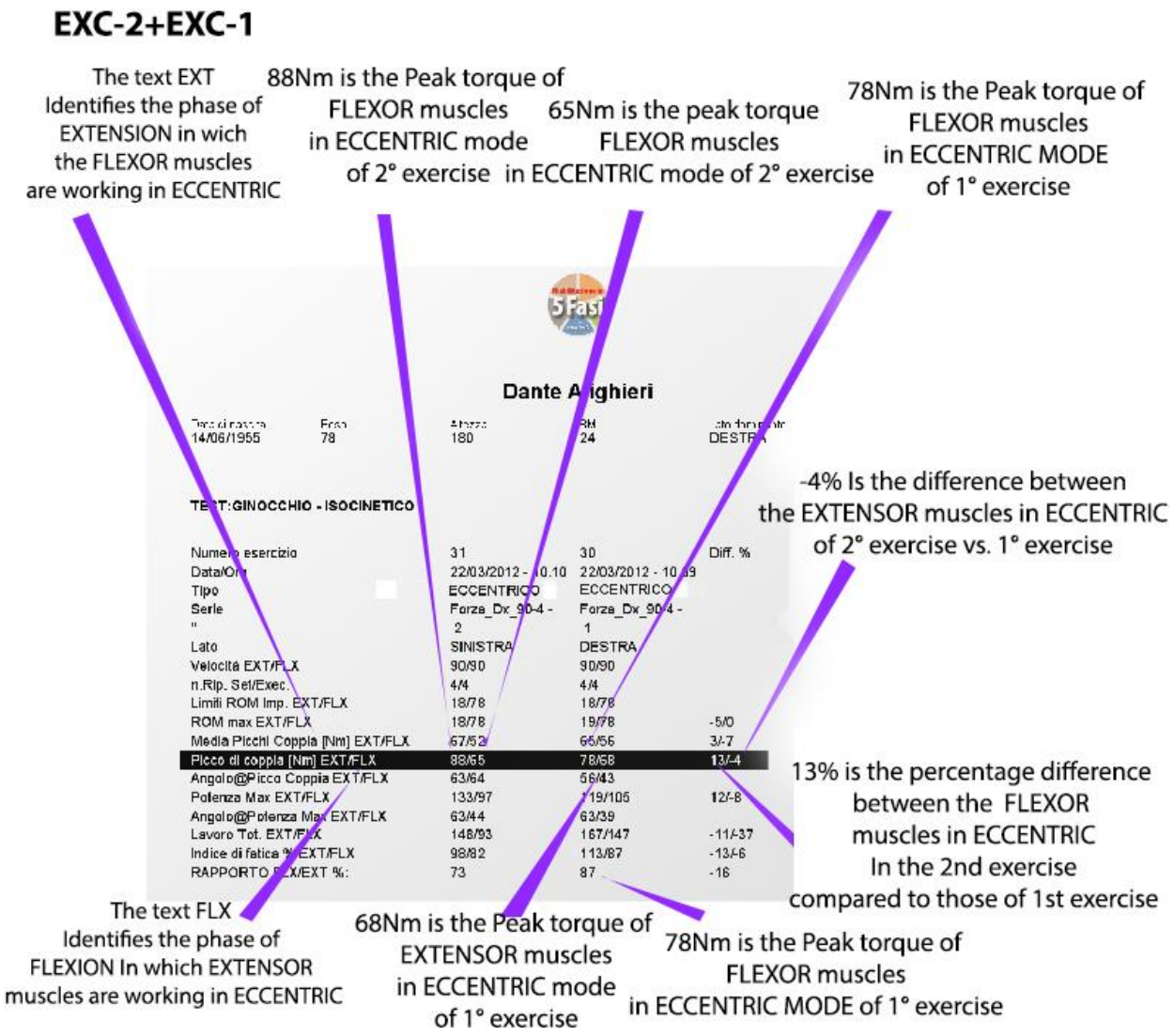
CNC-2+CNC-1


The text EXT Identifies the phase of EXTENSION in wich the EXTENSOR muscles are working in CONCENTRIC
88Nm is the Peak torque of EXTENSOR muscles in ECCENTRIC mode of 2° exercise
65Nm is the peak torque FLEXOR muscles in ECCENTRIC mode of 2° exercise
78Nm is the Peak torque of EXTENSOR muscles in ECCENTRIC MODE of 1° exercise
Dante Alighieri
-4% Is the percentage difference between the CONCENTRIC FLEXOR muscles In the 2nd exercise
13% is the percentage difference between the CONCENTRIC EXTENSORS muscles In the 2nd exercise compared to those of 1st exercise
The text FLX Identifies the phase of FLEXION In which FLEXOR muscles are working in CONCENTRIC
68Nm is the Peak torque of FLEXOR muscles in ECCENTRIC mode of 1° exercise
1st exercise: Relationship (ratio) between CONCENTRIC FLEXOR CONCENTRIC EXTENSOR

Numero esercizio	31	30	
Tipo	CONCENTRICO	CONCENTRICO	
Serie	2	1	
Lato	SINISTRA	DESTRA	
Velocità EXT/FLX	90/90	90/90	
n.Rip. Set/Exec.	4/4	4/4	
ROM max EXT/FLX	19/78	19/78	-5/0
Media Picchi Coppia [Nm] EXT/FLX	65/52	65/56	3/-7
Picco di coppia [Nm] EXT/FLX	88/65	78/68	13/-4
Angolo@Picco Coppia EXT/FLX	63/64	56/43	
Potenza Max EXT/FLX	133/97	119/105	12/-8
Angolo@Potenza Max EXT/FLX	63/44	63/39	
Lavoro Tot. EXT/FLX	148/93	167/147	-11/-37
Indice di fatica % EXT/FLX	98/82	113/87	-13/-6
RAPPORTO FLX/EXT %:	73	87	-16

In this case (relating to two CONCENTRIC exercises) the words EXT and FLX, which identify the phases of extension and flexion, refer to the Extensor and Flexor muscles.
This is the case shown in the box at the top left side in the Legend (see page 65), in the intersection between CNC-2 and CNC-1.

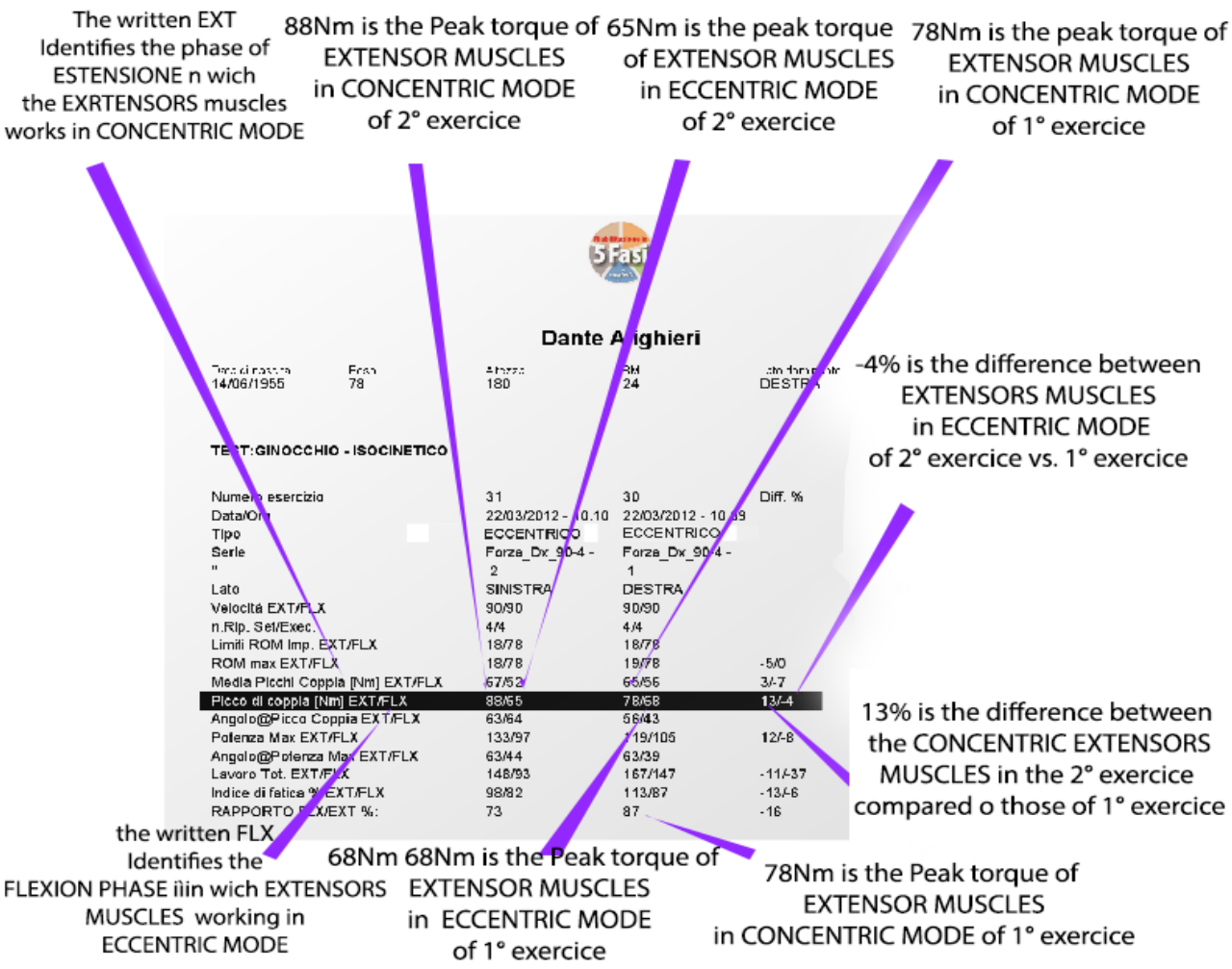
If the compared exercises are both ECCENTRIC, we have to take full account of what is expressed in the box next to the first one (the one between the intersection with EXC-2 and EXC-1) and we will see the following:


EXC-2+EXC-1
The text EXT Identifies the phase of EXTENSION in wich the FLEXOR muscles are working in ECCENTRIC
88Nm is the Peak torque of FLEXOR muscles in ECCENTRIC mode of 2° exercise
65Nm is the peak torque FLEXOR muscles in ECCENTRIC mode of 2° exercise
78Nm is the Peak torque of FLEXOR muscles in ECCENTRIC MODE of 1° exercise
Dante Alighieri
14/06/1955
78
180
24
DESTRA
TEST:GINOCCHIO - ISOCINETICO
Numero esercizio 31 30 Diff. %
Data/Ora 22/03/2012 - 10.10 22/03/2012 - 10.19
Tipo ECCENTRICO ECCENTRICO
Serie Forza_Dx_90-4 - 2 Forza_Dx_90-4 - 1
Lato SINISTRA DESTRA
Velocità EXT/FLX 90/90 90/90
n.Rip. Set/Exec. 4/4 4/4
Limiti ROM Imp. EXT/FLX 18/78 18/78
ROM max EXT/FLX 18/78 19/78 -5/0
Media Picchi Coppia [Nm] EXT/FLX 67/52 66/56 3/-7
Picco di coppia [Nm] EXT/FLX 88/65 78/68 13/-4
Angolo@Picco Coppia EXT/FLX 63/64 56/43
Potenza Max EXT/FLX 133/97 119/105 12/-8
Angolo@Potenza Max EXT/FLX 63/44 63/39
Lavoro Tot. EXT/FLX 148/93 167/147 -11/-37
Indice di fatica % EXT/FLX 98/82 113/87 -13/-6
RAPPORTO FLX/EXT %: 73 87 -16
-4% Is the difference between the EXTENSOR muscles in ECCENTRIC of 2° exercise vs. 1° exercise
13% is the percentage difference between the FLEXOR muscles in ECCENTRIC In the 2nd exercise compared to those of 1st exercise
The text FLX Identifies the phase of FLEXION In which EXTENSOR muscles are working in ECCENTRIC
68Nm is the Peak torque of EXTENSOR muscles in ECCENTRIC mode of 1° exercise
78Nm is the Peak torque of FLEXOR muscles in ECCENTRIC MODE of 1° exercise

As seen in the Legend (page 65), the boxes of the diagonal compare exercises homogeneous with each other (two concentric and two eccentric, two extensors or tw flexors).
We now see the case of other two diagonal boxes.

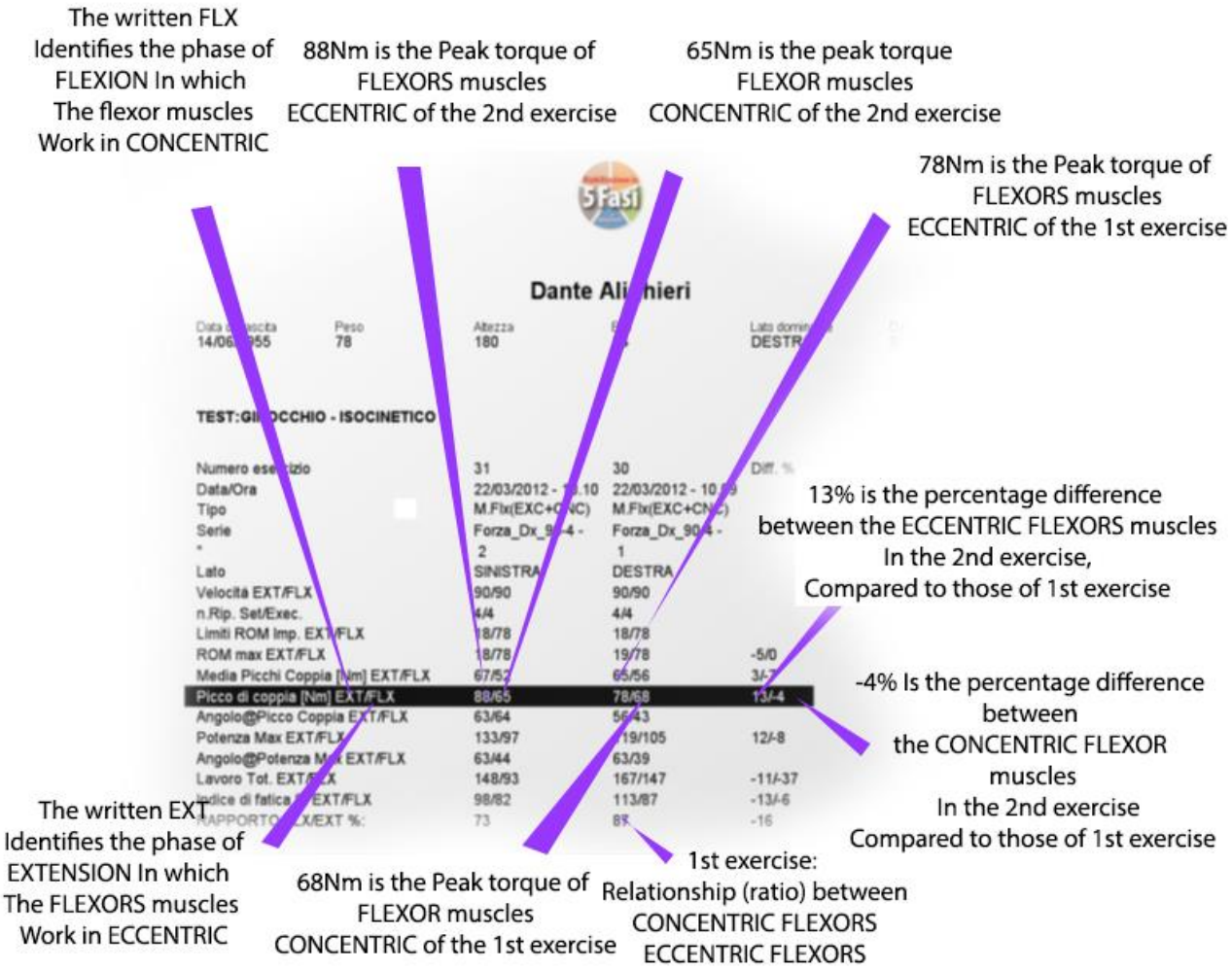
The following example is related to a test that compares two exercises both on EXTENSORS (Concentric + Eccentric)

M.Ext-2 + M.Ext-1


The written EXT Identifies the phase of ESTENSIONE n wich the EXRTENSORS muscles works in CONCENTRIC MODE
88Nm is the Peak torque of EXTENSOR MUSCLES in CONCENTRIC MODE of 2° exercice
65Nm is the peak torque of EXTENSOR MUSCLES in ECCENTRIC MODE of 2° exercice
78Nm is the peak torque of EXTENSOR MUSCLES in CONCENTRIC MODE of 1° exercice
Dante Alighieri
14/06/1955
78
180
24
DESTRA
TEST:GINOCCHIO - ISOCINETICO
Numero esercizio 31 30 Diff. %
Data/Ora 22/03/2012 - 10.10 22/03/2012 - 10.39
Tipo ECCENTRICO ECCENTRICO
Serie Forza_Dx_90-4 - Forza_Dx_90-4 -
" 2 1
Lato SINISTRA DESTRA
Velocità EXT/FLX 90/90 90/90
n.Rip. Set/Exec. 4/4 4/4
Limiti ROM Imp. EXT/FLX 18/78 18/78
ROM max EXT/FLX 18/78 19/78 -5/0
Media Picchi Coppia [Nm] EXT/FLX 67/53 66/56 3/-7
Picco di coppia [Nm] EXT/FLX 88/65 78/68 13/-4
Angolo@Picco Coppia EXT/FLX 63/64 56/43
Potenza Max EXT/FLX 133/97 119/105 12/-8
Angolo@Potenza Max EXT/FLX 63/44 63/39
Lavoro Tot. EXT/FLX 148/93 167/147 -11/-37
Indice di fatica % EXT/FLX 98/82 113/87 -13/-6
RAPPORTO FLX/EXT %: 73 87 -16
-4% is the difference between EXTENSORS MUSCLES in ECCENTRIC MODE of 2° exercice vs. 1° exercice
13% is the difference between the CONCENTRIC EXTENSORS MUSCLES in the 2° exercice compared o those of 1° exercice
the written FLX Identifies the FLEXION PHASE iiin wich EXTENSORS MUSCLES working in ECCENTRIC MODE
68Nm 68Nm is the Peak torque of EXTENSOR MUSCLES in ECCENTRIC MODE of 1° exercice
78Nm is the Peak torque of EXTENSOR MUSCLES in CONCENTRIC MODE of 1° exercice

The following example is related to a test that compares two exercises on both flexor (Concentric + Eccentric)

M.Flx-2+M.Flx-1



As seen in the legend (Pag. 65), the diagonal boxes compare exercises homogeneous with each other (two concentric and two eccentric, two extensors or two flexors).
The third column of the above report highlights the differences between two muscles equal that refer to the selected exercises, always taking as reference the first exercise carried out in order of time, the one which appears in the right column in the report.

IN CONCLUSION, THE PROGRAM ALLOWS YOU TO EASILY EVALUATE ALL PARAMETERS, PERFORMANCE REPORTS AND THE DIFFERENCES BETWEEN THE VARIOUS PARAMETERS MEASURED ON THE JOINTS INVOLVED. THE ROLE OF THE DOCTOR OR THERAPIST IS TO DECIDE ON THE EXERCISE TO BE CARRIED OUT FIRST AND SECOND, IN ORDER TO ACHIEVE THE DESIRED RESULTS.

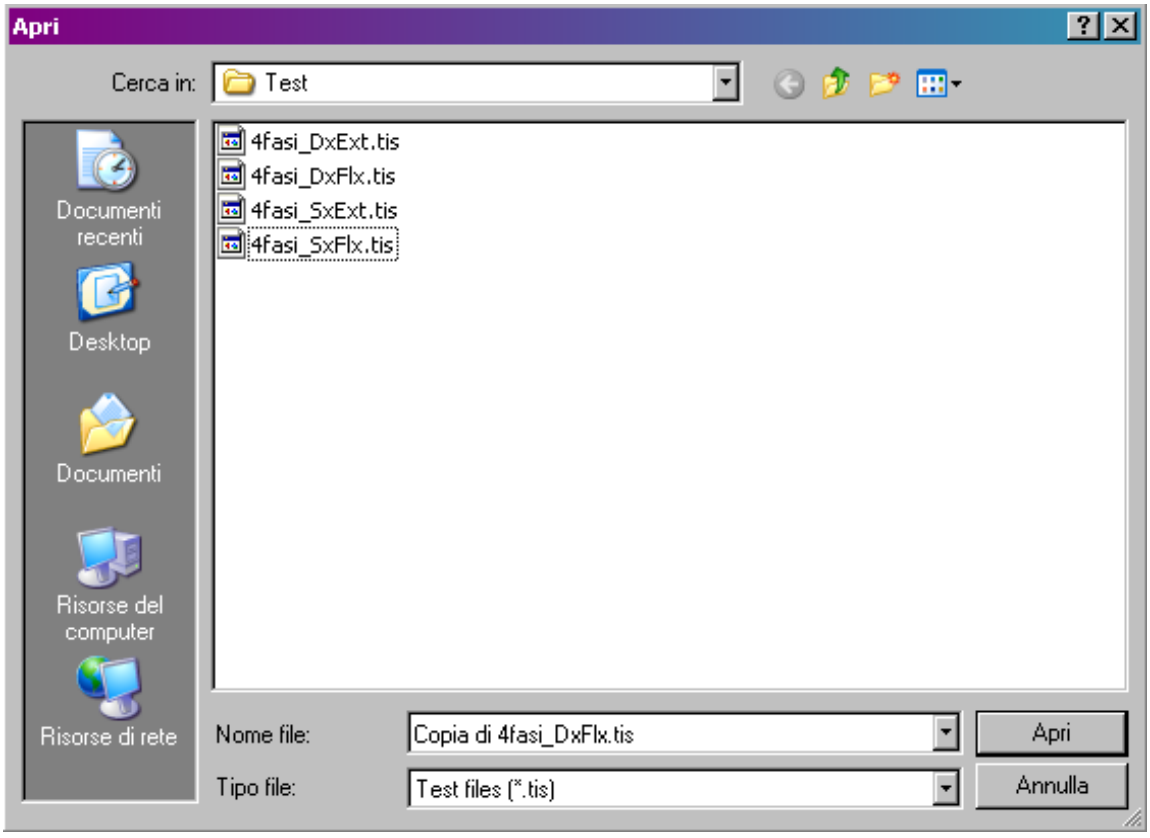
5.6.4.3 Isometric Test Report

An isometric test generally includes four exercises:

- Two exercises that have to be performed first (extension and flexion) with the healthy limb
- Two exercises that have to be performed immediately after the first ones (extension and flexion) with the sick limb

The isometric test must be performed at a specific angle, which can be selected manually as explained above. After this operation, it is necessary to select the desired type of test.
As shown in the following figure, there are 4 types of tests:

- 4Fasi_DxExt First exercise = Extension of the right limb
- 4Fasi_DxFlx First exercise = Flexion of the right limb
- 4Fasi_SxExt First exercise = Extension of the left limb
- 4Fasi_SxFlx First exercise = Flexion of the left limb

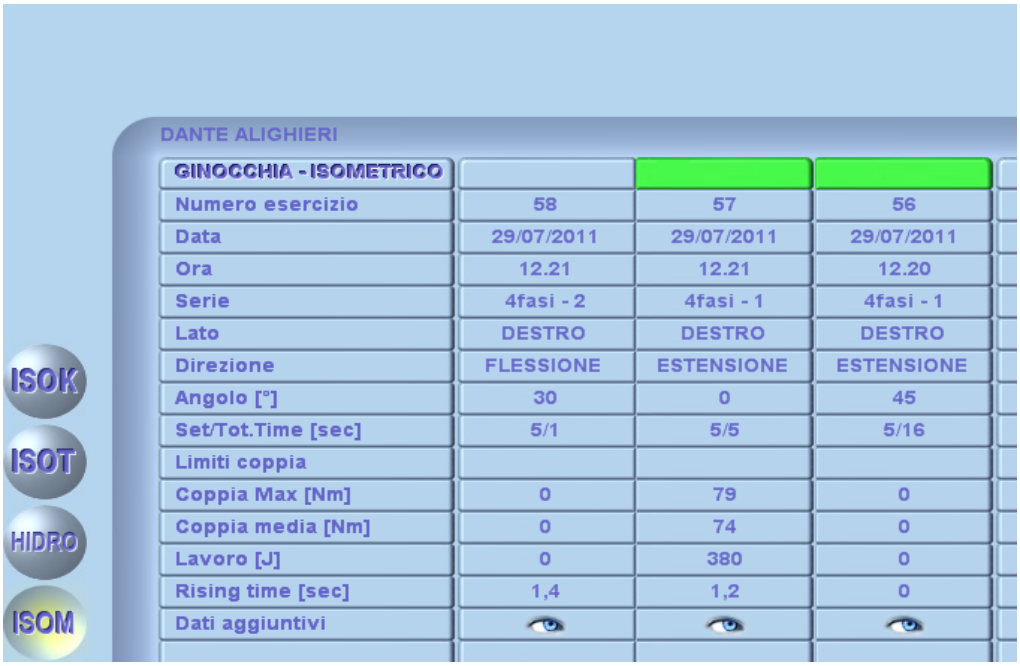


The 4 selected exercises will be performed in sequence, taking into account the required pauses and the time required to change the limb.

The final operation consists in opening the Database table and selecting one of the tests performed in order to view it or print the report.

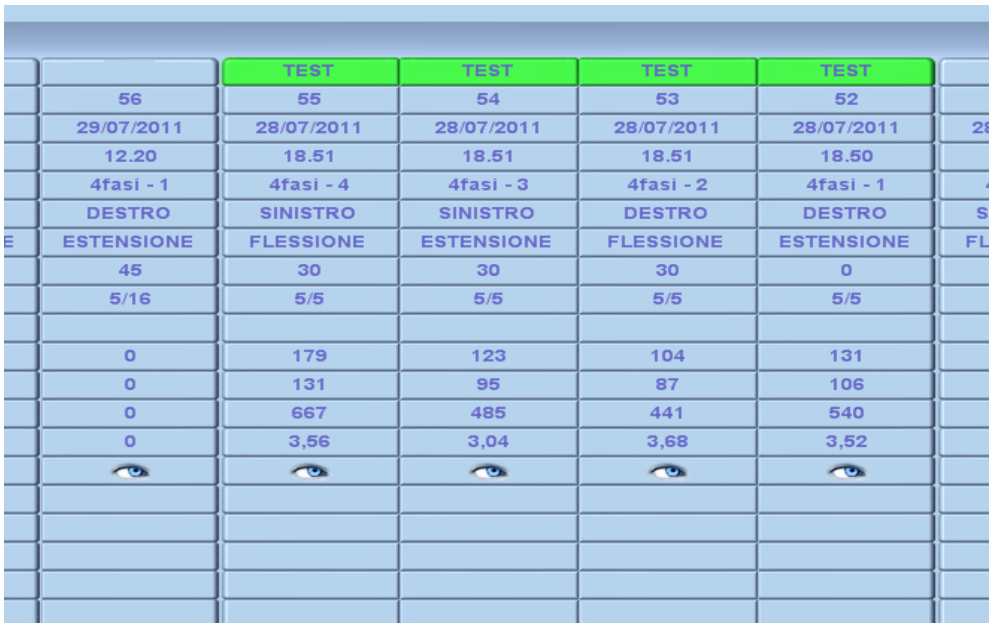
In the Database table, the tests can be selected in two ways:

- By clicking or touching any point in the column, it is possible to select a specific exercise; it is possible to select 1 or 2 exercises (see figure).



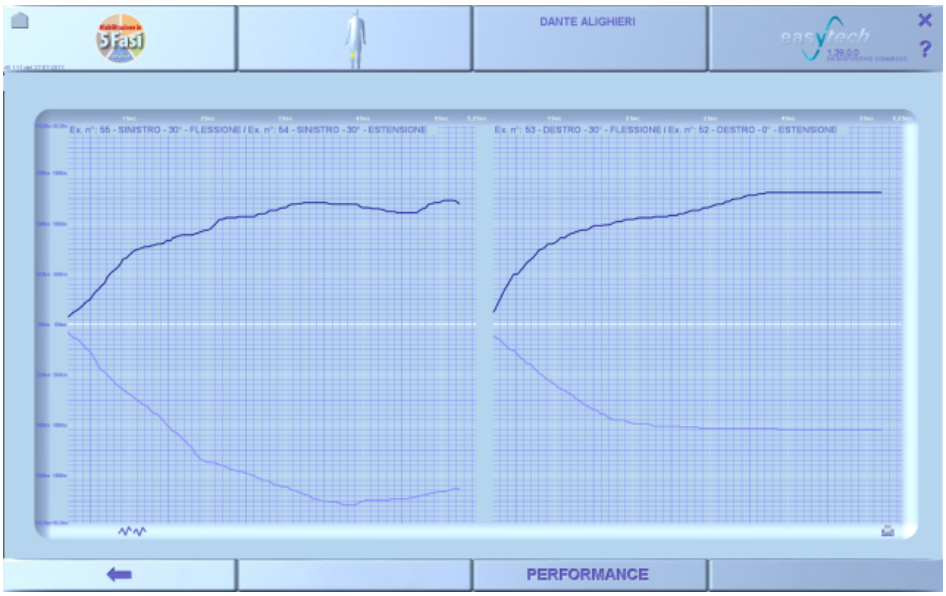
GINOCCHIA - ISOMETRICO			
Numero esercizio	58	57	56
Data	29/07/2011	29/07/2011	29/07/2011
Ora	12.21	12.21	12.20
Serie	4fasi - 2	4fasi - 1	4fasi - 1
Lato	DESTRO	DESTRO	DESTRO
Direzione	FLESSIONE	ESTENSIONE	ESTENSIONE
Angolo [°]	30	0	45
Set/Tot.Time [sec]	5/1	5/5	5/16
Limiti coppia			
Coppia Max [Nm]	0	79	0
Coppia media [Nm]	0	74	0
Lavoro [J]	0	380	0
Rising time [sec]	1,4	1,2	0
Dati aggiuntivi			

- By clicking or touching the header of a column and in particular the description “TEST”, it is possible to select all 4 test exercises (see figure)



	TEST	TEST	TEST	TEST	
56	55	54	53	52	
29/07/2011	28/07/2011	28/07/2011	28/07/2011	28/07/2011	28
12.20	18.51	18.51	18.51	18.50	
4fasi - 1	4fasi - 4	4fasi - 3	4fasi - 2	4fasi - 1	
DESTRO	SINISTRO	SINISTRO	DESTRO	DESTRO	S
ESTENSIONE	FLESSIONE	ESTENSIONE	FLESSIONE	ESTENSIONE	FL
45	30	30	30	0	
5/16	5/5	5/5	5/5	5/5	
0	179	123	104	131	
0	131	95	87	106	
0	667	485	441	540	
0	3,56	3,04	3,68	3,52	

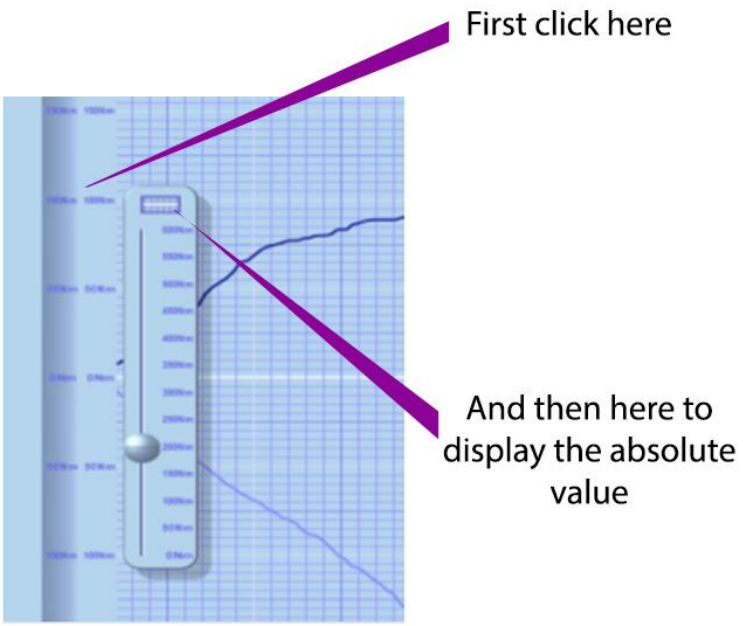
Button in the lower left side enables to display the charts.



The left section shows the data related to the limb involved in the exercise, while the right section refers to the reference contralateral limb (the healthy one).

The extension phase (positive convection) is displayed in the upper section of the chart, the zero line is displayed in the center, while the flexion (negative torque) is displayed in the lower section.

To accurately compare the extensor and flexor muscles of each limb, it is necessary to enable the display of absolute values (on the left of the chart) and click or touch the small rectangles above the scale control slider.



The zero line moves to the lowest section of the chart and the two curves are shown as absolute values. The dark curve refers to the extension values, while the lighter one shows the flexion one.
This simplifies the identification of the difference between flexor and extensor muscles.

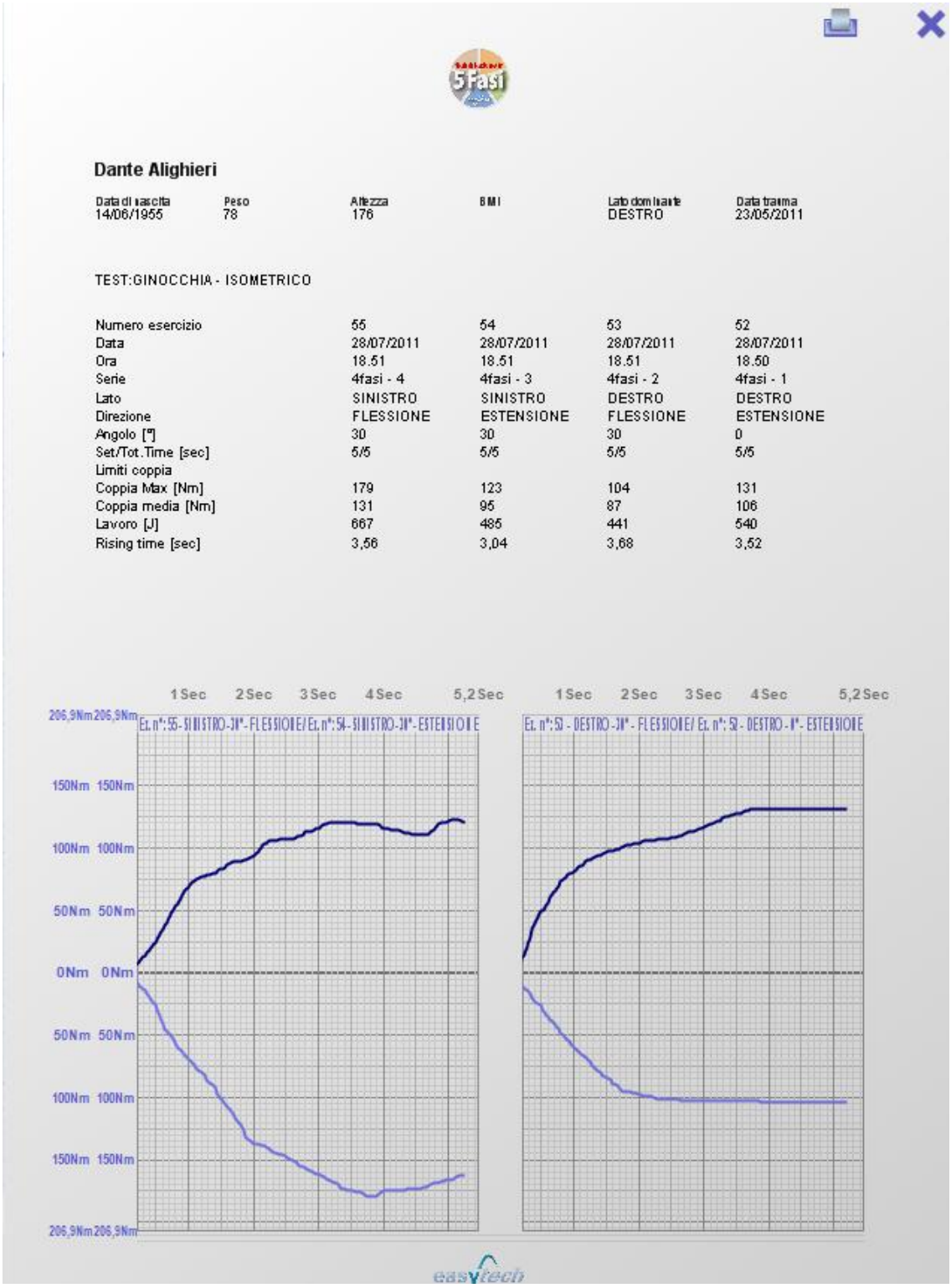
By clicking in the lower left side, it is possible to display the two overlapped charts and compare the torque values of one limb with those of the other one.

Continuous curves refer to the limb being examined while the dotted ones refer to the contralateral limb.

The printer icon in the lower right enables to print the two-page report: the first shows the data along with the charts selected on the screen.

The second shows all the differences (ratios and percentages) between:

- Extension and flexion of the limb being examined
- Extension and flexion of the contralateral limb
- Extension of the limb being examined and the contralateral limb
- Flexion of the limb involved in the exercise



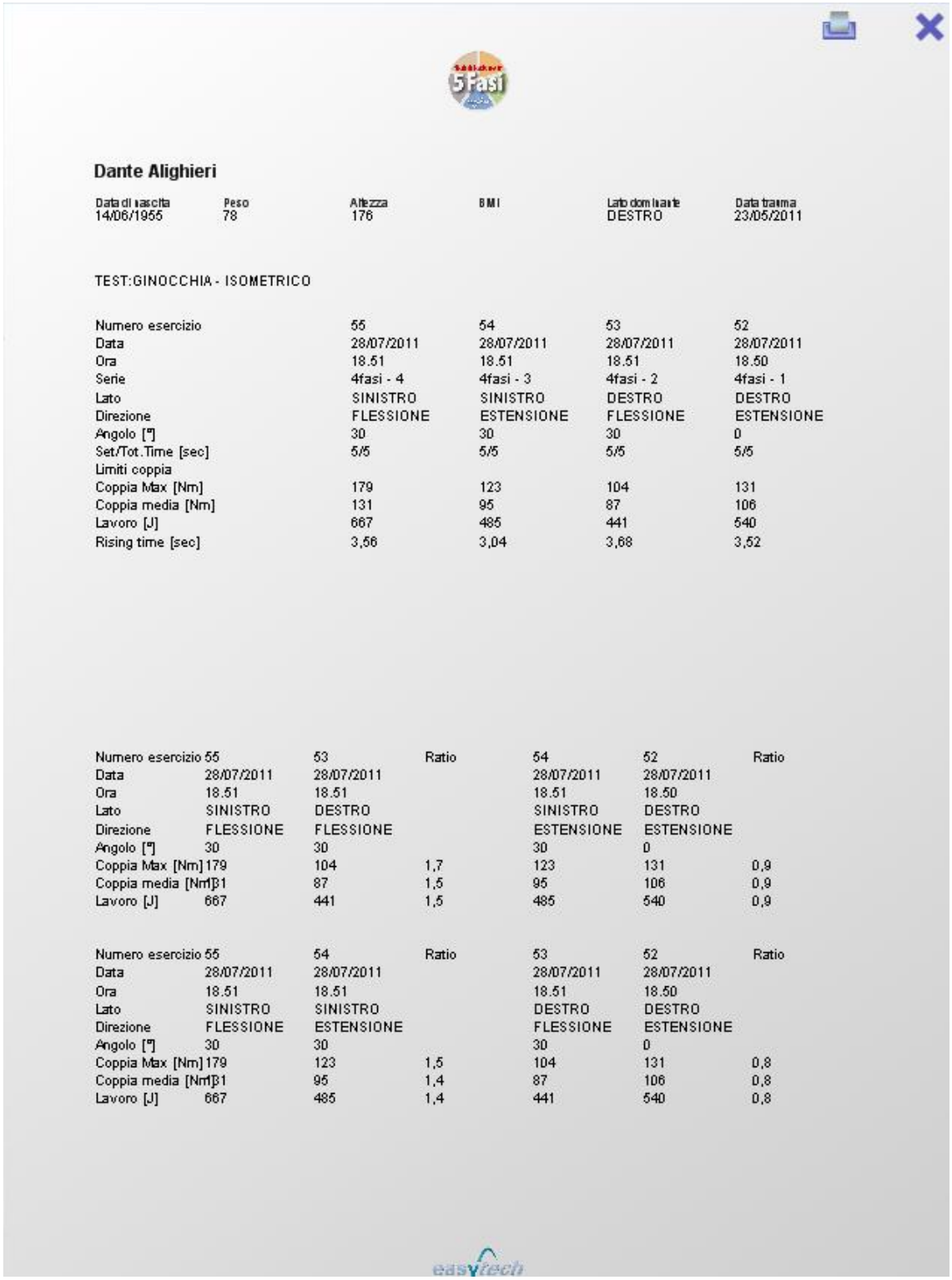
Dante Alighieri

Data di nascita	Peso	Altezza	BMI	Lato dominante	Data trauma
14/06/1955	78	176		DESTRO	23/05/2011

TEST:GINOCCHIA - ISOMETRICO

Numero esercizio	55	54	53	52
Data	28/07/2011	28/07/2011	28/07/2011	28/07/2011
Ora	18.51	18.51	18.51	18.50
Serie	4fasi - 4	4fasi - 3	4fasi - 2	4fasi - 1
Lato	SINISTRO	SINISTRO	DESTRO	DESTRO
Direzione	FLESSIONE	ESTENSIONE	FLESSIONE	ESTENSIONE
Angolo [°]	30	30	30	0
Set/Tot.Time [sec]	5/5	5/5	5/5	5/5
Limiti coppia				
Coppia Max [Nm]	179	123	104	131
Coppia media [Nm]	131	95	87	106
Lavoro [J]	667	485	441	540
Rising time [sec]	3,56	3,04	3,68	3,52

Click the printer icon in the upper right to print the report
Click the small cross on the far right to close the page.



Dante Alighieri

Data di nascita	Peso	Altezza	BMI	Lato dominante	Data trauma
14/06/1955	78	176		DESTRO	23/05/2011

TEST:GINOCCHIA - ISOMETRICO

Numero esercizio	55	54	53	52
Data	28/07/2011	28/07/2011	28/07/2011	28/07/2011
Ora	18.51	18.51	18.51	18.50
Serie	4fasi - 4	4fasi - 3	4fasi - 2	4fasi - 1
Lato	SINISTRO	SINISTRO	DESTRO	DESTRO
Direzione	FLESSIONE	ESTENSIONE	FLESSIONE	ESTENSIONE
Angolo [°]	30	30	30	0
Set/Tot.Time [sec]	5/5	5/5	5/5	5/5
Limiti coppia				
Coppia Max [Nm]	179	123	104	131
Coppia media [Nm]	131	95	87	106
Lavoro [J]	667	485	441	540
Rising time [sec]	3,56	3,04	3,68	3,52

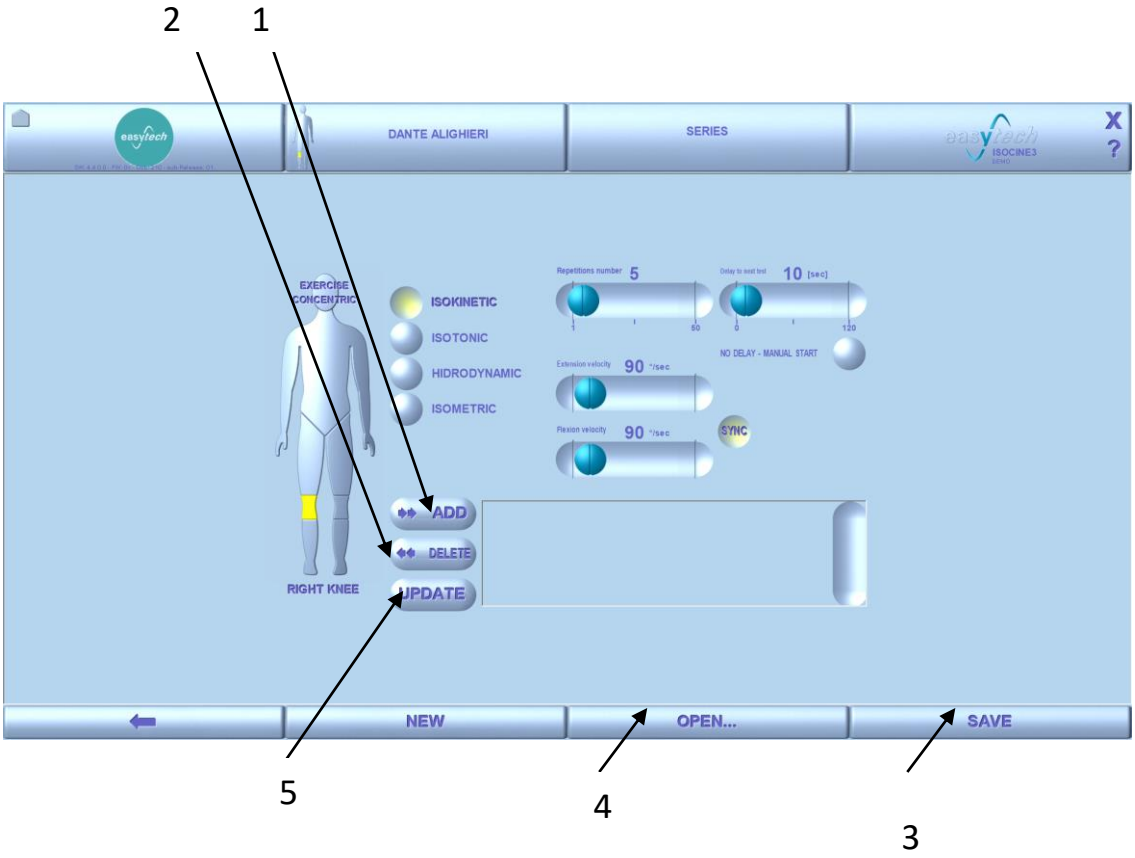
Numero esercizio	55	53	Ratio	54	52	Ratio
Data	28/07/2011	28/07/2011		28/07/2011	28/07/2011	
Ora	18.51	18.51		18.51	18.50	
Lato	SINISTRO	DESTRO		SINISTRO	DESTRO	
Direzione	FLESSIONE	FLESSIONE		ESTENSIONE	ESTENSIONE	
Angolo [°]	30	30		30	0	
Coppia Max [Nm]	179	104	1,7	123	131	0,9
Coppia media [Nm]	β1	87	1,5	95	106	0,9
Lavoro [J]	667	441	1,5	485	540	0,9

Numero esercizio	55	54	Ratio	53	52	Ratio
Data	28/07/2011	28/07/2011		28/07/2011	28/07/2011	
Ora	18.51	18.51		18.51	18.50	
Lato	SINISTRO	SINISTRO		DESTRO	DESTRO	
Direzione	FLESSIONE	ESTENSIONE		FLESSIONE	ESTENSIONE	
Angolo [°]	30	30		30	0	
Coppia Max [Nm]	179	123	1,5	104	131	0,8
Coppia media [Nm]	β1	95	1,4	87	106	0,8
Lavoro [J]	667	485	1,4	441	540	0,8

Click the printer icon in the upper right to print the report
Click the small cross on the far right to close the page.

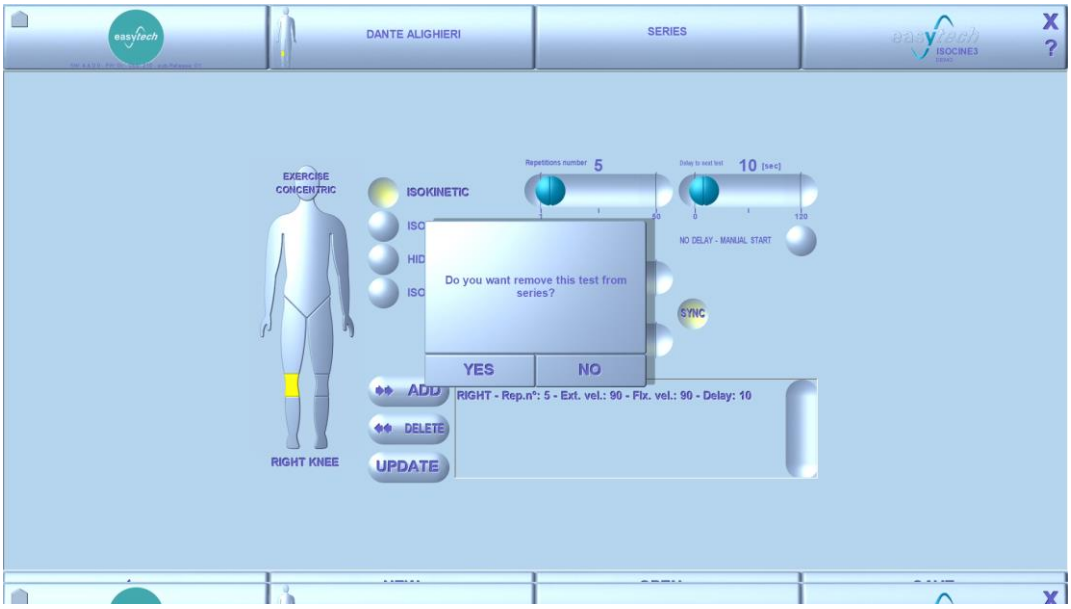
5.7 SETUP OF SERIES

The function is used to create a series of exercises for the patient. After selecting "SERIES EDITOR" and choosing the type of series (Concentric, Eccentric, PM), the following screen will appear for create a new series.

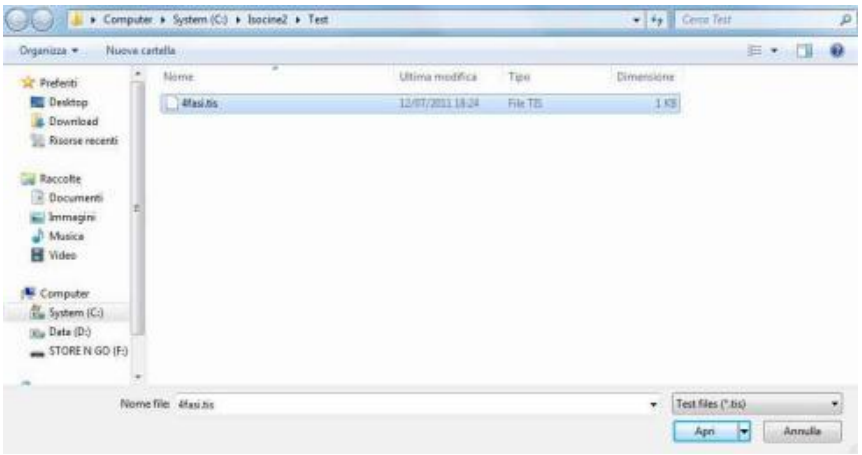


To create a new series, press "NEW", select the limb, the type of motion and its values. Confirm by pressing "ADD" (1) and repeat the operation until the desired series is created.

To delete an exercise from the series, select the exercise to be deleted, press "DELETE" (2) and confirm as shown in the following image.



After creating the series, press “SAVE” (3). The following window will appear where the created series will be named (max 10 alpha numeric characters).



The “UPDATE” button (5) allows the operator to update the data of a selected exercise.

To recall a previously saved series, press “OPEN” (4). A window will appear from which it is possible to recall the series of interest.

6. TROUBLESHOOTING

PROBLEM	CHECK TO BE PERFORMED	SOLUTION
GREEN LIGHT ON, THE POWER SWITCH OFF	Is there electric power on the plug where the device is installed?	- Contact our electrician.
	Is the power cable correctly connected on the device? Is it in good condition?	- Connect with care the power cord on the three-pole plug on the device. Control the power cable and eventually change it.
	Is the main fuse good?	- Checks the main fuse and replace if necessary, as described in cap. 4
ANOMALOUS LEVER MOVEMENTS (STEPS MOVEMENTS)	Low battery.	- Leave the device connected to grid, with the main switch in ON position, some hours without use it.
	Exhausted Batteries.	- Change the batteries.
	Air may be present in the hydraulic circuit	- Follow the air elimination described in the cap. 4.4.2
IT'S NO POSSIBLE TO EXECUTE A PM OR EXCENTRIC EXERCICE, THE DEVICE DON'T START	Low battery	- Leave the device connected to grid, with the main switch in ON position, some hours without use it.
	Exhausted Batteries.	- Change the batteries.
THERE IS AN OFFSET ON COUPLE VALUE	It's necessary to reset the torque offset.	Follow the procedure described in the cap 4.4.3
NO CONNECTION BETWEEN DEVICE AND PC	Control the emergency stop button, it must be lifted	Put the button in lifted position, as indicated by the arrows
	Control the USB cable, it must be well inserted in the plug	Connect with care the USB cable
	Maybe it's necessary restart the device and the PC	Switch off the device and the PC. Execute this operation following the order: control and eventually reconnect the USB cable – switch on the PC (leave the operating system start) – switch on the device – start the program

7. MAINTENANCE

This chapter describes the ordinary maintenance operations that are required to maintain Isokinetic Line Devices in optimal operating conditions.
Some mechanical parts (cable of the drive system, levers) tend to get moderately worn over time and should therefore be periodically (annually) inspected by the Technical Support.

The user is not expected to open any of the device covers for maintenance operations.

7.1 CLEANING THE EXTERNAL SURFACES

- **Switch the device off** by pressing the button in the rear section.
- **Disconnect the 220 V supply plug from the wall socket in the room. After performing this operation, also inspect the cable (see paragraph 2.3).**
- The seat and base of the device can be cleaned with a cloth dampened in water or another not aggressive detergent/disinfectant, provided that no liquid is actually spilled on these parts during cleaning.
- Avoid spraying liquids especially on the guards of the device that do not have a specific protection.
- Do not use solvents or the other abrasive solutions.
- Do not use heat/pressure sterilization systems.

7.2 PERIODICAL INSPECTION AND LIFE OF THE DEVICE

As suggested in the safety requirements, it is very important to perform a few visual/tactile checks every time the device is used in order to make sure its operative conditions are safe and that there are no visible damages.

- Check that the power cord is in good condition and has not been bent or crashed and that its external insulation is not damage otherwise replace it with an identical one (see chapter 2.2).
- Check the correct operation of the emergency stop button and the power switch.
- Some mechanical parts (cables of the transmission system, levers, belts, safety covers, adjustment knobs etc.) are subject to a slight wear. Therefore, it is advisable to have them regularly inspected (once a year) by the technical support.

In the event that some of these components are damaged, contact the **Easytech assistance service** and **do not use** the device before the replacement of the damaged component by Easytech or by an authorized service center.

Easytech guarantees the maintenance of the device for 5 years after its sale (law provision).

8. PACKAGING AND TRANSPORTATION OF THE DEVICE

8.1 PACKAGING AND TRANSPORTATION OF THE UNIT

To transport the unit over longer distances, it is advisable to place it on a Europallet (80 x 120 cm) using wood blocks and screws to fix it in place.

Lock the seat and back in an appropriate position (depending on the dimensions of the means of transport).

Lift the device with an appropriate mean and place it on a pallet, remove the caps that cover the fixing holes on the inferiors base plates and block the device on the pallet with 4 bolt M10 of suitable length equipped with large washers and nuts.

Protect the most exposed parts with expanded foam and cardboard, then wrap semi-adhesive film around the whole assembly.

The other parts of the machine can be packaged in a similar manner or placed in boxes.

8.2 ENVIRONMENTAL AND CONDITION FOR TRANSPORTATION AND STORAGE

Environment Temperature: [-10 ÷ + 50] °C
Relative Humidity: [30 ÷ 75] %
Atmospheric Pressure: [700 ÷ 1060] mbar

9. DISPOSAL OF THE UNIT AT THE END OF ITS LIFECYCLE

The disposal of the unit generally consists in simply replacing it and in returning the old one to the manufacturer for disposal.

If this is not feasible, it is necessary to dispose of the unit in accordance with current law provisions concerning electric and electronic equipment (Directive WEEE 2012/19/UE).

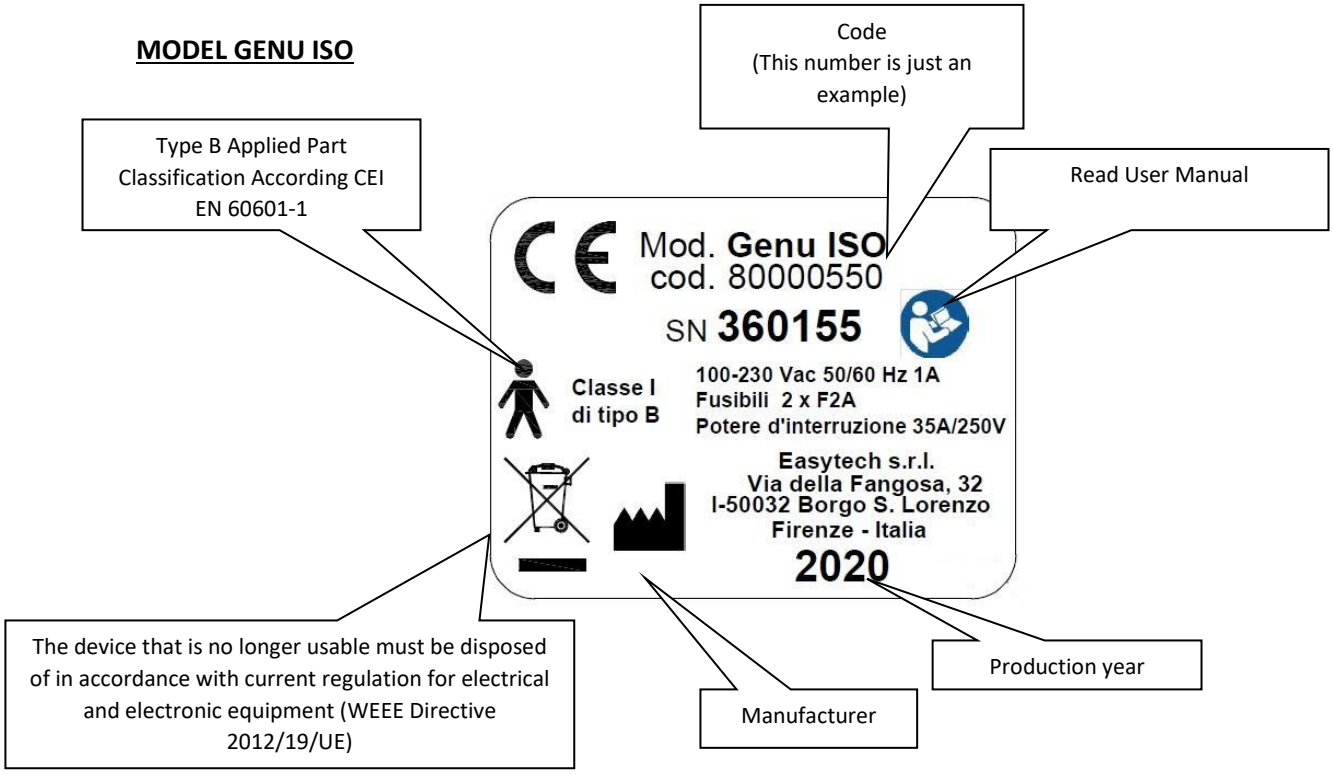
Please remember that the only part that requires special considerations in terms of disposal is the liquid of the hydraulic actuator (gear oil "Transmission fluid DX" by Agip Petroli S.p.A.), which is like the lubricating oil of a vehicle.

In this case, it is necessary to make sure that the person who collects the unit is aware of the content and able to dispose of it accordingly.

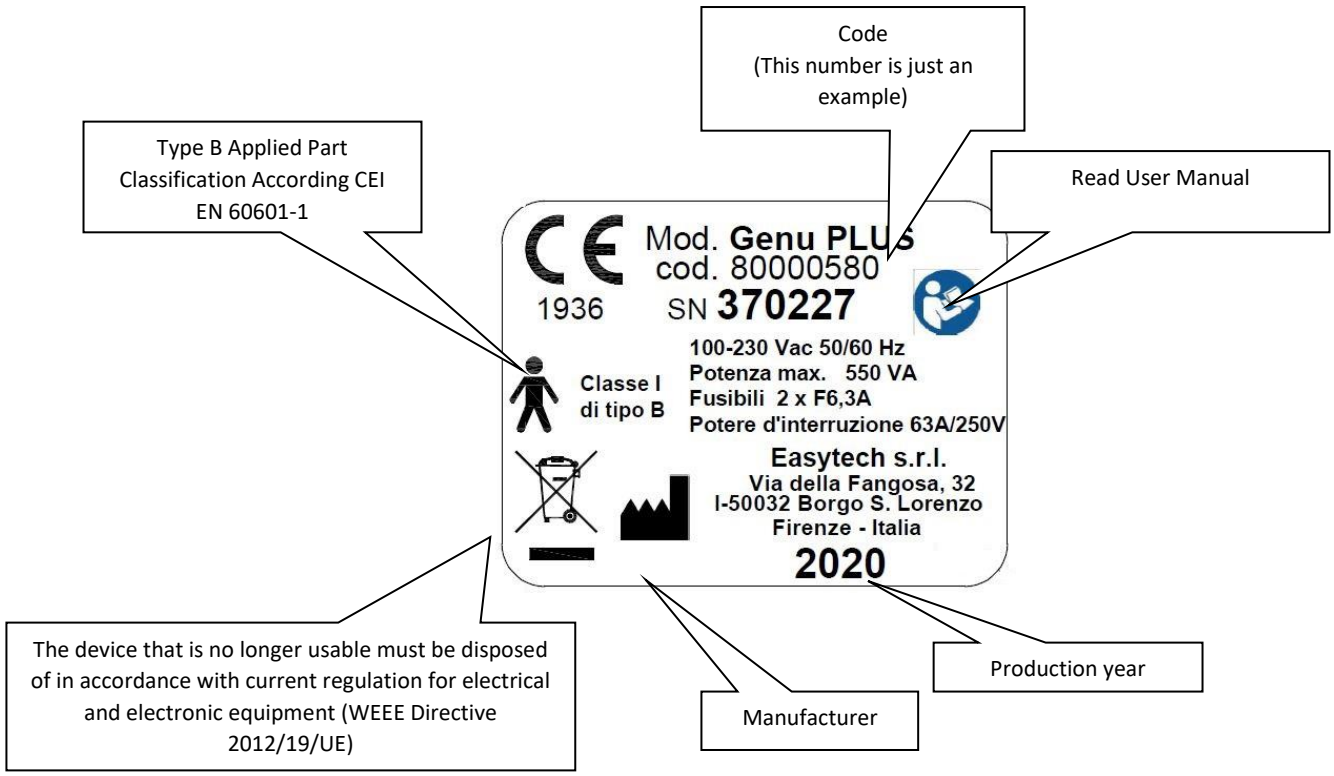
10. LABEL

In the lower side of the equipment there are some labels with basic information:

MODEL GENU ISO


Code
(This number is just an example)
Type B Applied Part Classification According CEI EN 60601-1
Read User Manual
Mod. Genu ISO
cod. 80000550
SN 360155
Classe I
di tipo B
100-230 Vac 50/60 Hz 1A
Fusibili 2 x F2A
Potere d'interruzione 35A/250V
Easytech s.r.l.
Via della Fangosa, 32
I-50032 Borgo S. Lorenzo
Firenze - Italia
2020
The device that is no longer usable must be disposed of in accordance with current regulation for electrical and electronic equipment (WEEE Directive 2012/19/UE)
Manufacturer
Production year

MODEL GENU PLUS


Code
(This number is just an example)
Type B Applied Part Classification According CEI EN 60601-1
Read User Manual
Mod. Genu PLUS
cod. 80000580
1936
SN 370227
Classe I
di tipo B
100-230 Vac 50/60 Hz
Potenza max. 550 VA
Fusibili 2 x F6,3A
Potere d'interruzione 63A/250V
Easytech s.r.l.
Via della Fangosa, 32
I-50032 Borgo S. Lorenzo
Firenze - Italia
2020
The device that is no longer usable must be disposed of in accordance with current regulation for electrical and electronic equipment (WEEE Directive 2012/19/UE)
Manufacturer
Production year

OTHER SYMBOLS THAT MAY BE ON THE DEVICE:

- READ USER MANUAL

- EQUIPOTENTIAL CONNECTION NODE

- EMERGENCY STOP BUTTON

LABELS AVAIABLE OF SERVICE

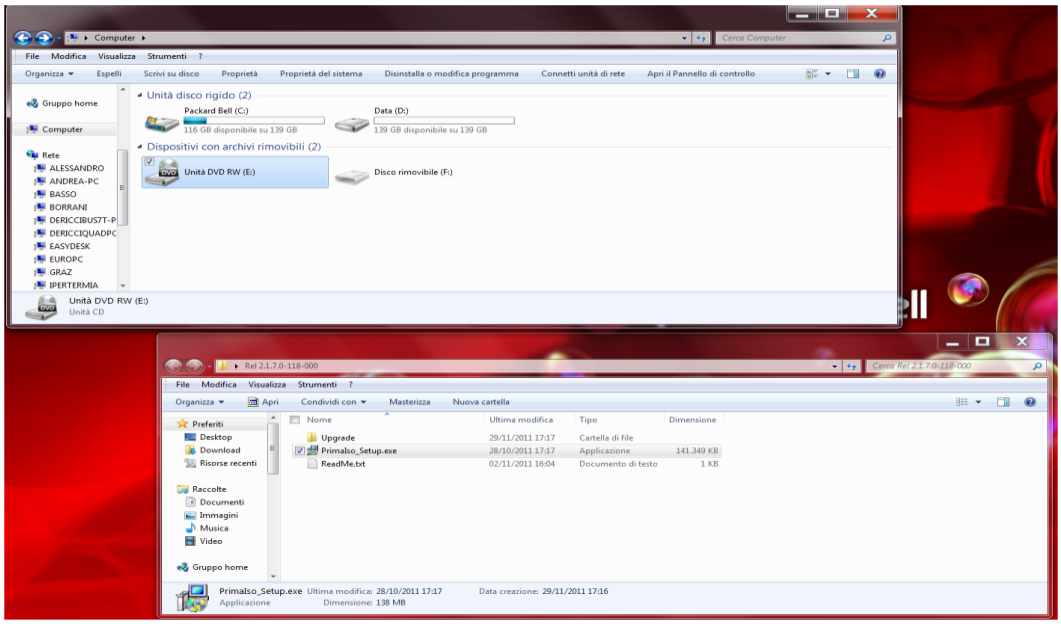
11.APPENDIX 1: SOFTWARE INSTALLATION

The installation process consists on the only ISOCINE3 installation program because no USB driver are needed for the communication.

11.1 PROGRAM INSTALLATION

Do not connect the USB cable to the computer.

Insert the installation CD or the USB pen into the device.

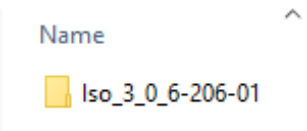


Note: If you are using the USB drive, you should create a new folder on hard disk of your computer.

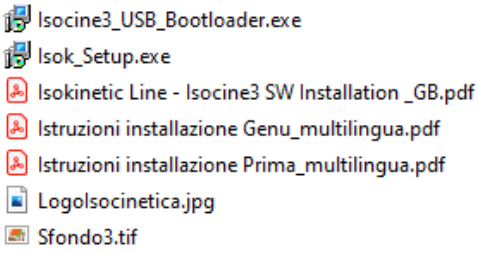
You should copy the USB drive's file into the new folder.

Open the unit DVD-RW, or the folder just created on your computer with the software inside.

Open file on folder – (the last numbers may change depending on the software release)

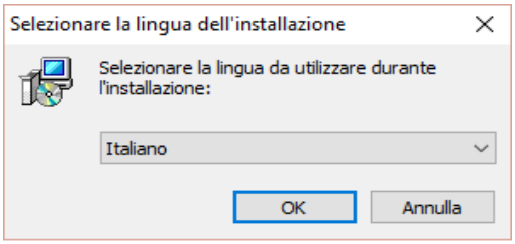


when you double click this folder it shows you the folowing



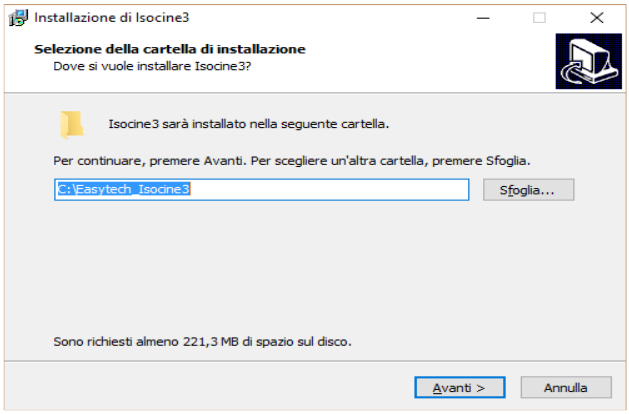
Select file Isok_Setup.exe, and with double click run the program.

A window like this will appear:



Select your favorite installation language and then click “OK “.

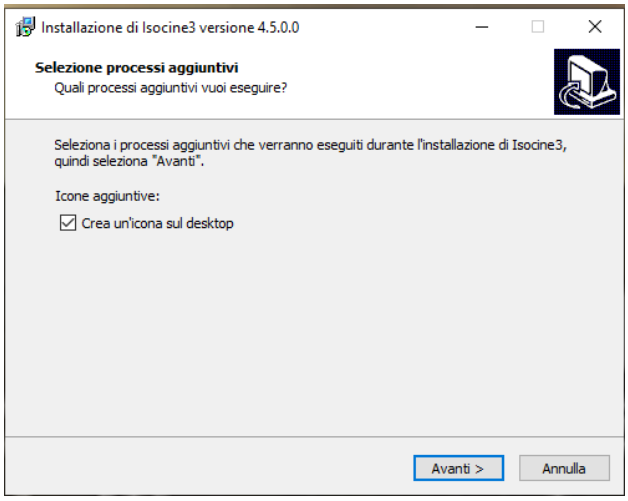
A window like this will appear:


Installazione di Isocine3
Selezione della cartella di installazione
Dove si vuole installare Isocine3?
Isocine3 sarà installato nella seguente cartella.
Per continuare, premere Avanti. Per scegliere un'altra cartella, premere Sfoglia.
C:\Easytech_Isocine3
Sfoglia...
Sono richiesti almeno 221,3 MB di spazio sul disco.
Avanti >
Annulla

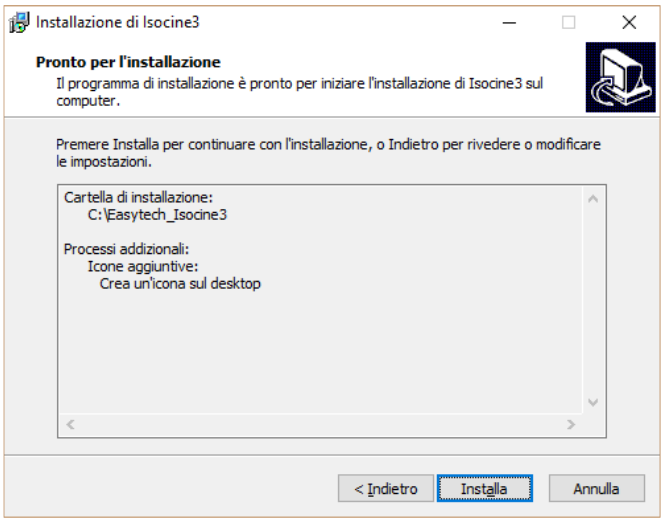
Choose the destination folder and then click “Next”.

<u>Note:</u> it is suggested not to change the default destination folder in order to guarantee the proper working!!!

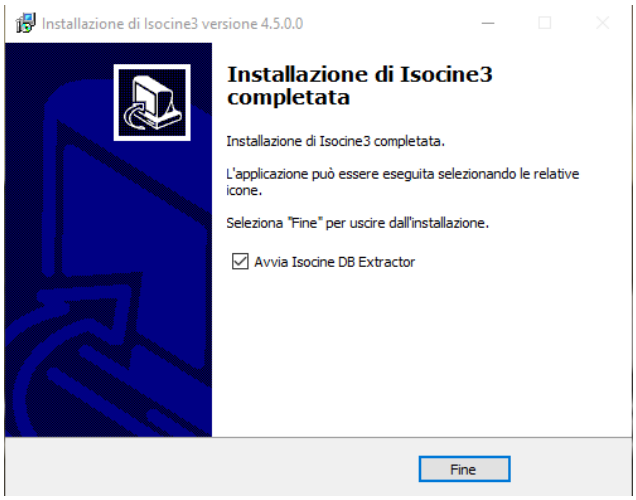
On the next window, check the checkbox and then click “Next”:


Installazione di Isocine3 versione 4.5.0.0
Selezione processi aggiuntivi
Quali processi aggiuntivi vuoi eseguire?
Seleziona i processi aggiuntivi che verranno eseguiti durante l'installazione di Isocine3, quindi seleziona "Avanti".
Icone aggiuntive:
Crea un'icona sul desktop
Avanti >
Annulla

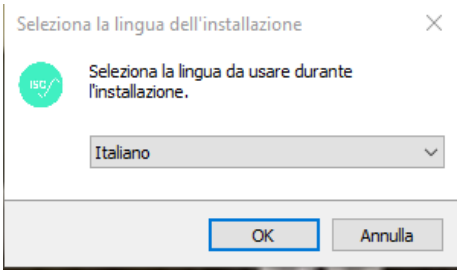
On the following window click “Install” and wait for the installation process to complete:


Installazione di Isocine3
Pronto per l'installazione
Il programma di installazione è pronto per iniziare l'installazione di Isocine3 sul computer.
Premere Installa per continuare con l'installazione, o Indietro per rivedere o modificare le impostazioni.
Cartella di installazione:
C:\Easytech_Isocine3
Processi addizionali:
Icone aggiuntive:
Crea un'icona sul desktop
< Indietro
Installa
Annulla

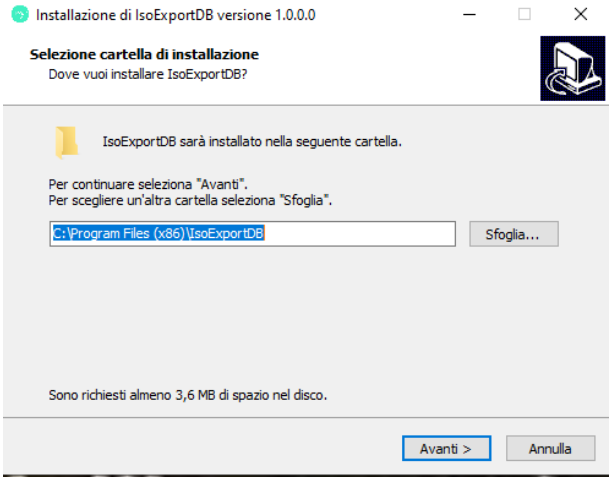
When the process is completed, click on **“Finish”** to start the installation of the exercise extraction tool from a common Isocine3 archive.


Installazione di Isocine3 versione 4.5.0.0
Installazione di Isocine3 completata
Installazione di Isocine3 completata.
L'applicazione può essere eseguita selezionando le relative icone.
Seleziona "Fine" per uscire dall'installazione.
Avvia Isocine DB Extractor
Fine

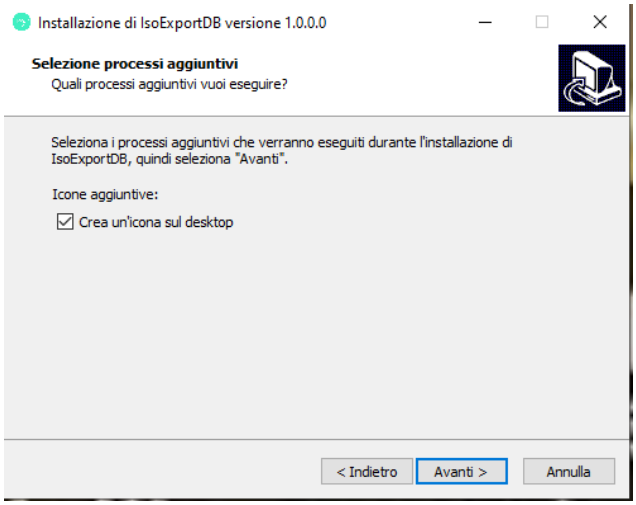
Select installation language and click on **OK.**



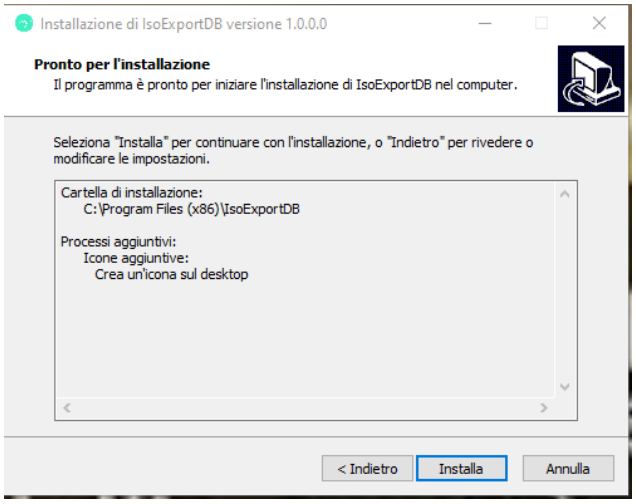
If the installer requests to choose the installation folder, leave the default one then click on **Next.**


Installazione di IsoExportDB versione 1.0.0.0
Selezione cartella di installazione
Dove vuoi installare IsoExportDB?
IsoExportDB sarà installato nella seguente cartella.
Per continuare seleziona "Avanti".
Per scegliere un'altra cartella seleziona "Sfoglia".
C:\Program Files (x86)\IsoExportDB
Sfoglia...
Sono richiesti almeno 3,6 MB di spazio nel disco.
Avanti >
Annulla

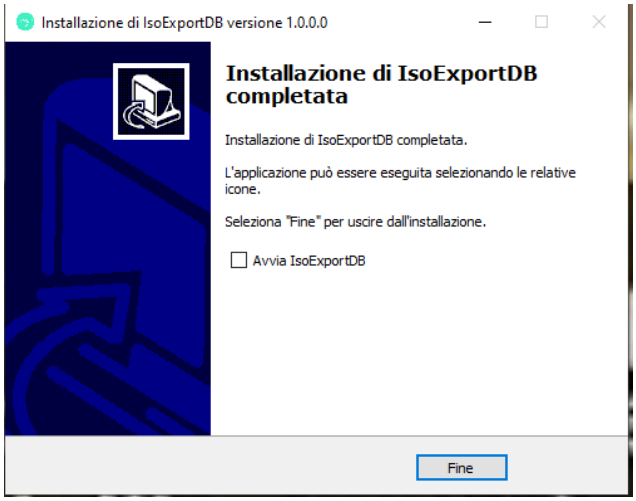
In the next step, leave the checkmark on **"Create a desktop shortcut"** then click on **Next.**


Installazione di IsoExportDB versione 1.0.0.0
Selezione processi aggiuntivi
Quali processi aggiuntivi vuoi eseguire?
Seleziona i processi aggiuntivi che verranno eseguiti durante l'installazione di IsoExportDB, quindi seleziona "Avanti".
Icone aggiuntive:
Crea un'icona sul desktop
< Indietro
Avanti >
Annulla

In the next step, click on **Install.**


Installazione di IsoExportDB versione 1.0.0.0
Pronto per l'installazione
Il programma è pronto per iniziare l'installazione di IsoExportDB nel computer.
Seleziona "Installa" per continuare con l'installazione, o "Indietro" per rivedere o modificare le impostazioni.
Cartella di installazione:
C:\Program Files (x86)\IsoExportDB
Processi aggiuntivi:
Icone aggiuntive:
Crea un'icona sul desktop
< Indietro
Installa
Annulla

As the tool installation is completed, click on **Finish.**


Installazione di IsoExportDB versione 1.0.0.0
Installazione di IsoExportDB completata
Installazione di IsoExportDB completata.
L'applicazione può essere eseguita selezionando le relative icone.
Seleziona "Fine" per uscire dall'installazione.
Avvia IsoExportDB
Fine

The Isocine3 software installation is now completed.

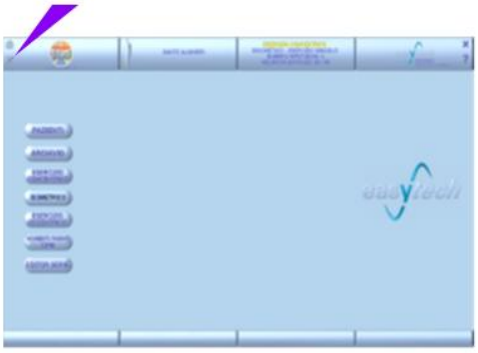
11.2 START PROGRAM

Start Isocine3 program.

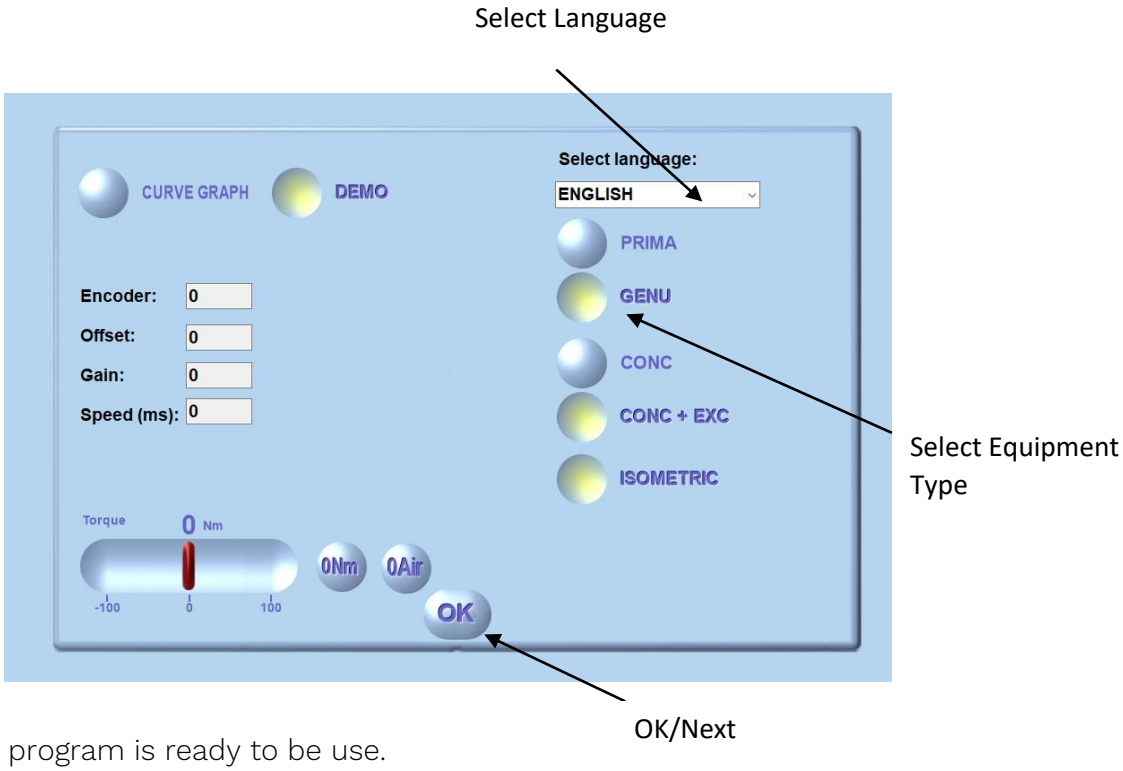
Open the program by double clicking on desktop icon:

Now open the program configuration panel to complete the installation:

Click on this icoun to access setup



Digit the password 2016, then click OK



The program is ready to be use.

Now is possible to use the equipment.

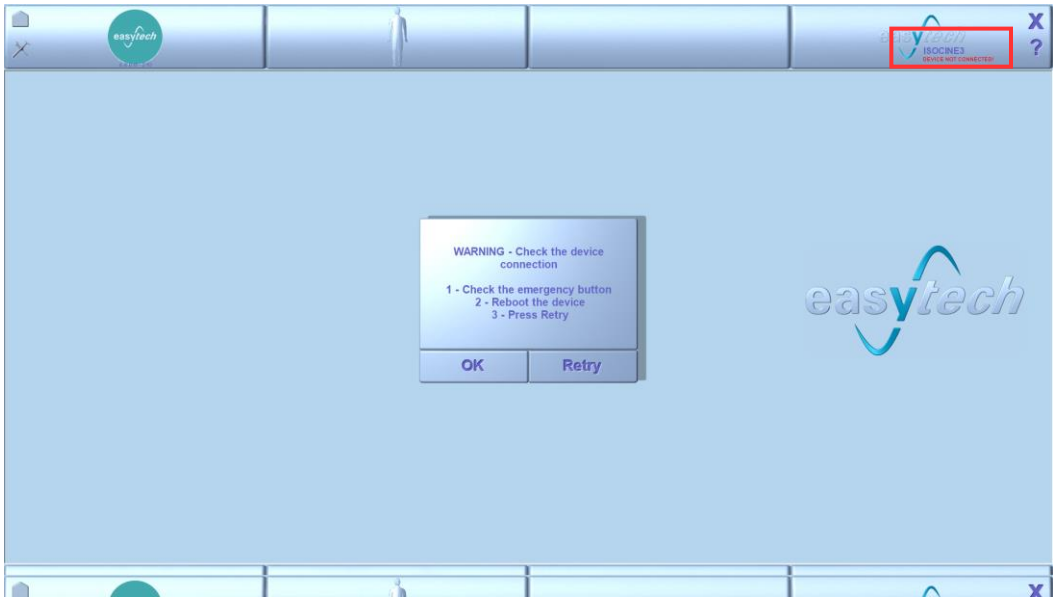
Please read the user manual carefully.

To open the user manual, click the left button or tap the screen by selecting the question mark in the upper right corner.

11.3 START PROGRAM WITH ERROR MESSAGE

If running the program Isocine3 for the first time, you receive the following error message, it means that device is not connected.

In the picture below there is a red font on the right top below the easytech logo (Device not connected).



Possible causes can be:

1. The USB Cable is not connected to the computer
2. The device is not turned on
3. The emergency button is pressed

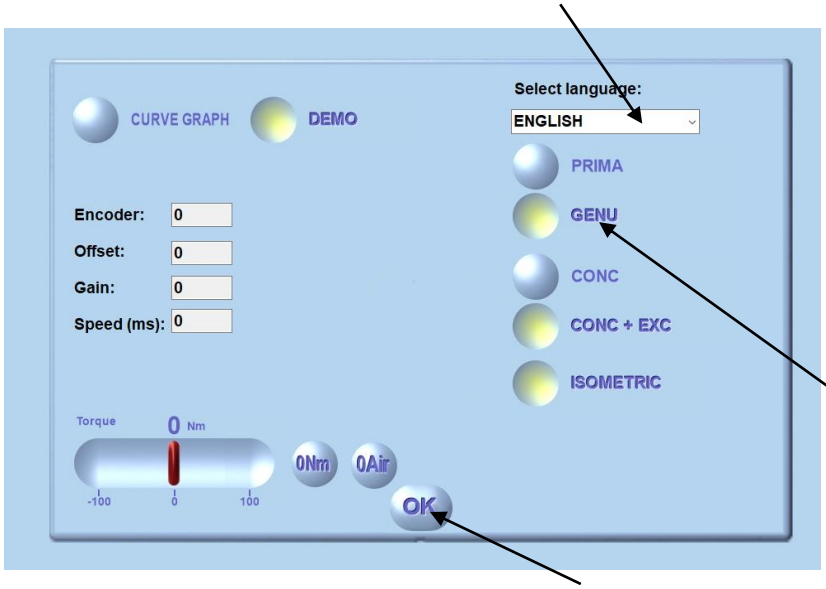
Check the USB connection, turn on the device or release the emergency button and press “Retry”.
Close the program, then open the software again.
See picture below (status icon) in order to verify the device connection.

Now open the program configuration panel to complete the installation:

Click on this icoun to access setup

Digit the password 2016, then click OK

Select Language



Select Equipment Type

OK/Next

Now the program is correctly configured.
Now is possible to use the equipment.

PLEASE READ THE USER MANUAL CAREFULLY. TO OPEN THE ONLINE USER MANUAL CLICK WITH LE LEFT BUTTON OR TOUCH THE SCREEN BY SELECTING THE QUESTION MARK IN THE UPPEN RIGHT CORNER.

12. APPENDIX 2: EXTERNAL TOOLS

The Isocine3 software also includes three different software tools adding specific functionalites to the software itself.

12.1 IsoDateExSync

The *IsoDateExSync* tool is located in the *Utilities* folder of the Isocine3 software installation directory. By default the path is as follows:

C:\Easytech_Isocine3\Utilities\IsoDateExSync

This tool is intended to be used to correct any errors in displaying the date of the saved exercises in the Isocine3 software archive.

Please refer to the user's manual in the folder itself ("Mus_IsoDateExSync_IT.pdf" or "Mus_IsoDateExSync_GB.pdf").

12.2 IsoExportDB

The *IsoExportDB* tool is located in the *Utilities* folder of the Isocine3 software installation directory. By default the path is as follows:

C:\Easytech_Isocine3\Utilities\IsoExportDB

This tool is intended to be used to extract, in offline mode from an exercise archive of the Isocine3 software, a detailed list of all the exercises performed by a specific patient with the relative performances for each exercise..

Please refer to the user's manual in the folder itself ("Mus_IsoExportDB_IT.pdf" or "Mus_IsoExportDB_GB.pdf").

12.3 Report Customization

User can customize the report by choosing to display or hide specific items related to the performance of the exercise.

User need to open, with a generic text editor, the following file:

C:\Easytech_Isocine3\CfgIsocine.ini

Now user have simply to change the value of a certain item to display it (value=1) or hide it (value=0).

Please refer to the user's manual in the folder itself:

C:\Easytech_Isocine3\Utilities\Isocine3 _ Report Customization.xls

DECLARATION OF CONFORMITY

The product

Genu ISO

CE

complies with the provision of Annex I of Council Directive 93/42 EEC of 14 June 1993 concerning medical devices, published in the Official Gazette of the Italian Republic on 25 October 1993 and acknowledged in Italy through Legislative Decree No.46 on 24 February 1997 and subsequent amendments and additions.

The product is a Class **I** active medical device in accordance with Rule 1, Annex IX of European Directive 93/42/EEC

Borgo San Lorenzo, 1/3/2019

(Ing. Stefano Basso)

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DECLARATION OF CONFORMITY

Directive 93/42/EEC

The product

Genu Plus

CE 1936

complies with the provision of Annex I of Council Directive 93/42 EEC of 14 June 1993 concerning medical devices, published in the Official Gazette of the Italian Republic on 25 October 1993 and acknowledged in Italy through Legislative Decree No.46 on 24 February 1997 and subsequent amendments and additions.

The product is a Class **II b** therapeutic active medical device in accordance with Rule 9, Annex IX of European Directive 93/42/EEC.

Borgo San Lorenzo, 1/3/2019

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